

**UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.**

**Before The Honorable Clark S. Cheney
Administrative Law Judge**

In the Matter of

CERTAIN COLOR INTRAORAL
SCANNERS AND RELATED HARDWARE
AND SOFTWARE

Investigation No. 337-TA-1091

**RESPONDENTS 3SHAPE A/S, 3SHAPE TRIOS A/S, AND 3SHAPE INC.'S
POST-HEARING RESPONSIVE BRIEF**

Exhibit No.

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'207 Patent	Asserted U.S. Patent No. 8,675,207.
'228 Patent	Asserted U.S. Patent No. 8,363,228.
'433 Patent	Asserted U.S. Patent No. 9,101,433.
'456 Patent	Asserted U.S. Patent No. 8,451,456.
'470 Patent	Asserted U.S. Patent No. 6,685,470.
'931 Patent	Asserted U.S. Patent No. 6,948,931.
3PHB	3Shape's Initial Post-Hearing Brief.
3PreHB	3Shape's Pre-Hearing Brief.
3Shape	3Shape A/S, 3Shape Trios A/S, and 3Shape, Inc.
Accused Software	3Shape's Ortho System and Dental System Software.
Accused Products	3Shape's Accused Software and Trios 3.
Align	Align Technology, Inc.
APHB	Align's Initial Post-Hearing Brief.
APreHB	Align's Pre-Hearing Brief.
Asserted Patent(s)	The '207 Patent, '228 Patent, '433 Patent, '456 Patent, '470 Patent, and '931 Patent, individually and/or collectively.
CDO	Cease and desist order.
CMA	Certified Management Accountant.
Color Scanning Patents	The '207 Patent, '228 Patent, '433 Patent, and '456 Patent, individually and/or collectively.
CPA	Certified Public Accountant.
Element	iTero Element, Element 2, and Element Flex, individually and/or collectively.

GAAP	Generally Accepted Accounting Principals.
Gingival Deformation Patents	The '470 Patent and '931 Patent, individually and/or collectively.
HT	Hearing transcript.
IP	Intellectual property.
LEO	Limited Exclusion Order.
SEC	U.S. Securities and Exchange Commission.
Trios	3Shape's Trios and Trios 3 intraoral scanners, individually and/or collectively.

I. INTRODUCTION

This Investigation is the story of an old company with stale technology trying to stem the rising tide of its upstart competitor and their superior product. While iTero may have been the market leader over a decade ago, Trios has been the best-in-class technology since 2013. (HT 721:25-722:8.) In an effort to salvage its iTero market and stem the tide that saw Trios sales more than double in the U.S. from 2016-2017, Align sued 3Shape as a pretext to halt competition, devising unsupported copying, infringement, and domestic industry stories.

In addition to the clear evidence that 3Shape had no intent to copy, Trios uses a fundamentally different color scanning approach than both iTero and the Color Scanning Patents. Unlike those patents, neither Trios nor iTero utilizes a “hand-held device comprising...a processor configured to associate the depth data with the color image data.” Nor does Trios contain the “scanning system” or “imaging system” claimed in the patents. Align similarly attempts to shoehorn the accused and domestic products under the Gingival Deformation Patents, despite the fact that none of the products utilize the required secondary gingival model.

In addition to its inability to satisfy the technical prong, Align cannot satisfy the economic prong. Because of Align’s focus on Invisalign, it was forced to depart from financial reality in counting various non-cognizable investments toward its domestic industry, allocating an unsupported amount of those investments to iTero, and assessing significance based on overstatement of the numerators, understatement of the denominators, and qualitative factors unsupported by the evidence. In support, every Align domestic industry witness gave testimony that is contrary to the contemporaneous evidence, and thus unreliable.

For these and the other reasons explained herein, Align has failed to prove any violation of Section 337 by 3Shape.

II. JURISDICTION AND IMPORTATION

A. Accused Software¹

Align has not established that 3Shape imports the Accused Software.² As of March 2018, 3Shape ships Trios from Poland to 3Shape's Branchburg, New Jersey depot, "where the Ortho [System] software will be flashed on and then sent to the reseller." (HT 1157:12-22.)³ Similarly, 3Shape's unaccused lab scanners are also "produced or manufactured in [3Shape's] facility in Poland," shipped "to the Branchburg office where the [Accused] software is flashed on, and then from there it's shipped to the reseller." (HT 1158:17-1159:4.) Once an end user receives a Trios or lab scanner, she requires a dongle to activate any software functionality. (HT 1159:11-17.) The dongle is an "activation code for using the software," it does not contain the Accused Software. (HT 1159:18 – 1160:5.) Finally, all updates/upgrades of Accused Software and standalone Accused Software are provided exclusively by electronic download over the internet. (See HT 840:10-15, JX-0054C 117:19-20, 22; JX-0066C 212:13-19, 217:15-224:25.)

Pursuant to Section 337 and the Federal Circuit's holding in *ClearCorrect Operating, LLC v. ITC*, these activities with respect to the Accused Software do not constitute importation of "articles that...infringe." 810 F.3d 1283, 1289-90 (Fed. Cir. 2015) (electronic transmissions of digital data that do not constitute "material thing[s]" or "articles that...infringe" under Section 337). "[W]hen there is no importation of 'articles' there can be no unfair act, and there is nothing for the Commission to remedy." *Id.* at 1290.

¹ 3Shape disputes that Dental System is properly accused. (See Section IV.B.1, *infra*.)

² 3Shape's Trios application software and ScanSuite Trios software are not discussed in Align's Post-Hearing Brief.

³ Trios scanners are not configured with Dental System software. (HT 1157:9-11.)

Align's reliance on *Suprema Inc. v. ITC*, 796 F.3d 1338 (Fed. Cir. 2015) and *Cisco Sys., Inc. v. ITC*, 873 F.3d 1354 (Fed. Cir. 2017) do not alter the analysis set forth in *ClearCorrect*. These cases are inapplicable to the Accused Software in light of *ClearCorrect*, because they concern "articles," and the Accused Software is not an "article" under Section 337. *See ClearCorrect*, 810 F.3d at 1289-1290. The cases are further distinguishable because Align has not accused the hardware 3Shape allegedly imports (*i.e.*, Trios, lab scanners, or dongles) of contributing to or inducing infringement in combination with Accused Software – Align's infringement allegations are directed exclusively to functionality of 3Shape's Ortho Analyzer software. This is necessary because the scope of the '470 patent, for instance, is limited to "[a] computer program." (JX-0001 8:2-17.)

B. 3Shape Inc.

3Shape Inc. does not import, sell for importation, or sell after importation into the U.S. any accused product, and thus has not committed a violation or unfair act. 3Shape Trios A/S owns the Trios scanners at all times before and after they are shipped to the U.S., including Trios Orthos sent to the Branchburg depot. (HT 1157:23-1158:7; JX-0071C 122:13-22; 209:24-210:11.) 3Shape A/S sells the Accused Software. (HT 1159:5-10; 1162:23-1163:11; JX-0054C, 117:19-22; JX-0066C 212:13-19.) Align intimates 3Shape Inc. may commit a violation because it "owns" the Branchburg facility (APHB at 8), but 3Shape Inc. never holds title to Accused Products. (JX-0389C at ¶ 6.)

Align also claims 3Shape Inc. is a proper Respondent based on its after-sales and sales support activities in training, warranty and repair, and trade show attendance, ignoring that 3Shape's resellers, not 3Shape Inc., sell the Accused Products. (*See* HT 764:9-13.) Align interprets a "sale after importation" too broadly. *See, e.g., Certain Semiconductor Devices*,

Semiconductor Device Packages, and Prods. Containing Same, Inv. No. 337-TA-1010, Order No. 69 (Feb. 27, 2017) *not reviewed* (“A ‘sale’ consists of the passing of title from the seller to the buyer for a price”) (quoting *Black’s Law Dictionary* (10th ed. 2014)). That a CDO may reach wholly domestic conduct “reflects the Commission’s exercise of its discretion to fashion an appropriate remedy,” not conduct that constitutes a violation of Section 337. *Id.* at 7.

Align has not established, and provides no supporting authority, that 3Shape Inc.’s activities constitute sufficient involvement in importation or sale of the Accused Products to invoke Commission jurisdiction. 3Shape Inc. has not committed a violation or unfair act. *See Certain Dynamic Random Access Memory and NAND Flash Memory Devices and Prods. Containing Same*, Inv. No. 337-TA-803, Order No. 66 at 4 (Aug. 21, 2012); *Certain Salinomycin Biomass and Preparations Containing Same*, Inv. No. 337-TA-370, 1995 ITC LEXIS 302, Order No. 9 at *6-9 (May 15, 1995) (“Where a party has not imported or sold accused products in the [U.S.], and does not intend to do so in the future, there is no violation of section 337.”).

C. 3Shape A/S

3Shape A/S does not import, sell for importation, or sell after importation any Accused Product. 3Shape A/S does not own or sell Trios products in the U.S. (*See* HT 1157:23-1158:7) and, for the reasons described above, 3Shape A/S’s U.S. activities do not constitute an unfair act pursuant to Section 337 with respect to Trios scanners. Also for the reasons described above, 3Shape’s A/S’s activities with respect to Accused Software do not constitute an unfair act. Thus, 3Shape A/S has committed no violation.

D. Standing

Align “bears the burden of establishing that it has standing.” *Certain Video Game Sys. and Controllers*, Inv. No. 337-TA-743, 2013 ITC LEXIS 1996, ID at *156 (Feb. 2013) *not*

reviewed in relevant part; 19 C.F.R. § 210.12(a)(7). Align sets forth no argument or evidence, only asserting that “Respondents do ‘not contest Align’s standing.’” (APHB at 9.) This does not meet Align’s burden.

III. THE COLOR SCANNING PATENTS

A. Claim Construction

1. “scanning system” (’228, ’456, ’207 patents, claim 1)

Align’s shifting interpretations of the elements comprising the claimed “scanning system” confirm that “scanning system” fails to recite sufficiently definite structure, and thus is subject to §112 ¶6. At the hearing, Align and its expert, Dr. Stevenson, identified main illumination source 31 and main optics 41 as the corresponding structures. (HT 530:23-533:6, 580:3-14; CDX-0008.23.) Yet, Align’s Post-Hearing Brief identifies Figures 4A and 4B as “one embodiment of the scanning system elements that provide depth data.” (APHB at 12.) Not only does the scanning system in Figures 4A-4B include main illumination source 31 and main optics 41, it also includes additional components including detection optics 60 and image processor 24. (JX-0003 at Figs. 4A and 4B.) Align’s inability to consistently identify the structures corresponding to the “scanning system” undermine its contention that it is a term of art.

Align’s “plain and ordinary” construction of “scanning system” as a 3D scanner is likewise unhelpful in shedding light on the particular structure of the scanning system. Indeed, Dr. Stevenson was uncertain whether the structure corresponding to “scanning system” under Align’s construction is a 3D scanner:

Q Did I understand correctly that the structure in the patents that corresponds to scanning system under Align's construction is a 3D scanner?

A I think that that was the construction for the image-gathering member maybe?

(HT 580:3-14.) Align's vague "plain and ordinary" constructions underscore the lack of definite structure connoted by "scanning system."

Align contends that "3Shape cannot overcome the presumption that §112 ¶6 does not apply." (APHB at 12.) In support, Align rewrites "scanning system" as "scanner system" to argue it is "not a nonce term." (*Id.*) Align then resorts to the specification to argue that one of ordinary skill "would conclude the patent denotes sufficiently definite structure or acts for performing the function." (*Id.*) But that is not the proper test of whether §112 ¶6 applies. "Sufficient structure exists when the claim language specifies the exact structure that performs the functions in question without need to resort to other portions of the specification or extrinsic evidence for an adequate understanding of structure." *TriMed, Inc. v. Stryker Corp.*, 514 F.3d 1256, 1259-60 (Fed. Cir. 2008). Align's resort to the specification highlights the lack of sufficient structure connoted by "scanning system."

Align attacks 3Shape's §112 ¶6 construction for (1) improperly inserting the requirement that depth data be separately obtained from 2D color image data and (2) requiring the structures identified in 3Shape's construction. That depth data must be separately obtained from 2D color image data is compelled by the specification and prosecution history. The specification notes that "a two dimensional (2D) color image of the 3D structure that is being scanned is also obtained, but typically within a short time interval with respect to the 3D scan," meaning depth data and color data are obtained at different times – *i.e.*, separately. (JX-0003 at 3:61-64.)

During prosecution, the patentee distinguished prior art that “obtain[ed] a series of two dimensional color images of an object and process[ed] those images to obtain a three dimensional model,” avoiding the need for a scanning system providing depth and a separate imaging system providing color image data. (JX-0009 at Align-1091_00003104; HT 1076:18-1078:5.) Dr. Stevenson did not consider or address this clear disclaimer.

The structures identified in 3Shape’s proposed construction correspond to the structures disclosed in the specification for the “scanning system.” Align argues that 3Shape is “reading the structure in from just one [embodiment] and ignoring all others” without explaining why 3Shape’s identified structures are not required by the “seven embodiments” in the specification. (APHB at 13.) 3Shape’s identified structures correspond to the only structures disclosed in the specification for “scanning system.”

Align’s interpretation of “depth data” as “data indicating depth in the three-dimensional space” is overly broad and inconsistent with the specification. Under Align’s interpretation, any data related to depth would constitute depth data. This is inconsistent with the plain claim language, which makes clear that the depth data is “of said portion of the three-dimensional structure.” In the specification, depth data is referenced in terms of the object’s Z-coordinate. (JX-0003 at 3:30-37, 3:53-58, 13:25-31, Fig. 2A-2C.) Further, the plain claim language requires depth data to be associated with color image data. The only depth data described as being associated is the object’s Z-coordinate. (*See, e.g.*, JX-0003 at 13:20-62; Figs. 2A-2C.) There is no suggestion of any other “data indicating depth” that is associated with color.

2. “imaging system” (’228, ’456, and ’207 patents, claim 1)

Align’s interpretation of “imaging system” as an image sensor or detector is insufficient structure for performing the claimed function of “provid[ing] two-dimensional color image

data.” The specification consistently describes that the two-dimensional color image is provided by the image sensor and the illumination source that captures the color image. (*See, e.g.*, JX-0003 at 24:43-47 (“In each of the embodiments described herein, the illumination radiation that is used for obtaining the 2D color image is injected into the optical axis OA of the confocal optics 42 without affecting the operation thereof or degrading the 3D image capture.”).) Align’s citations to the specification describe inclusion of an illumination source to capture the 2D color image. (APHB at 14.) The experts agreed that an illumination source is required to create an image. (HT 539:3-540:18; 1068:15-1069:6.) Thus, Align’s recitation of an image sensor as the “imaging system” does not connote sufficient structure.

Align contends that “system... simply connotes that the ‘imaging system’ may include optical components beyond just an image sensor.” This interpretation is vague and highlights the lack of specific structure Align ascribes to “imaging system.”

Align contends that 3Shape’s construction is improper because it requires that two-dimensional color image data be separately obtained from depth data. However, as previously discussed, that limitation is compelled by the specification and prosecution history. Likewise, 3Shape’s identified structure is consistent with the intrinsic record and understanding of a person of ordinary skill.

3. “processor” (’228, ’456, and ’207 patents, claim 1)

The claimed “processor” is subject to §112 ¶6 because the recited function – “associate the depth data with the color image data” – cannot be performed without specific programming. This is evidenced by the specification, which describes that color association “may be executed on any suitable microprocessor means, typically processor 24 of the device 100 (FIG. 4B).” (*See* JX-0003 at 14:32-35.) In other words, association requires a computer programmed to perform

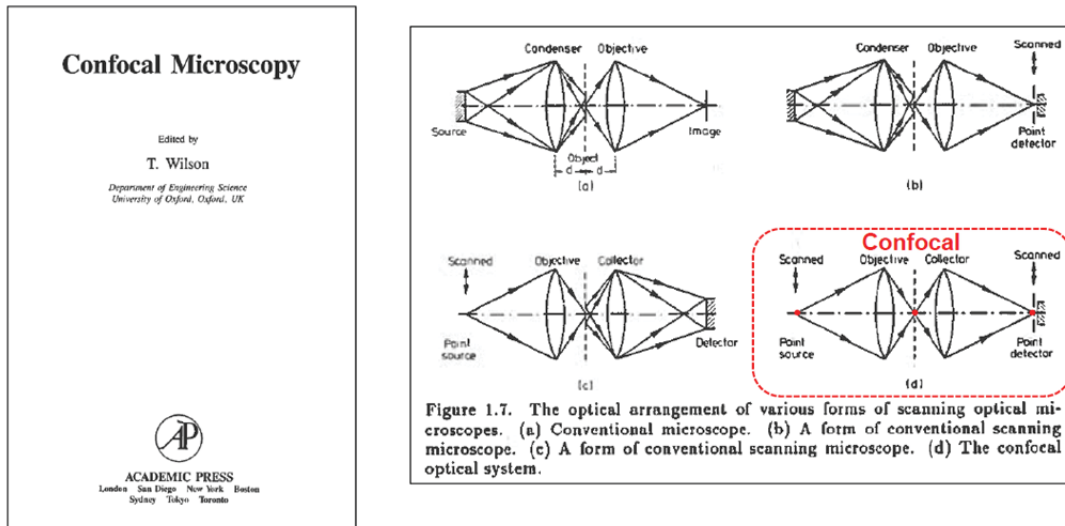
that function. Thus “processor” is subject to §112 ¶6. *See Finisar Corp. v. DirecTV Grp., Inc.*, 523 F.3d 1323, 1340 (Fed. Cir. 2008) (quoting *WMS Gaming, Inc. v. Int’l Game Tech.*, 184 F.3d 1339, 1349 (Fed. Cir. 1999)) (“For computer-implemented means-plus-function claims where the disclosed structure is a computer programmed to implement an algorithm, ‘the disclosed structure is not the general purpose computer, but rather the special purpose computer programmed to perform the disclosed algorithm.’”). Align provides no evidence that the association can be performed by a generic processor to avoid §112 ¶6.

Align contends that 3Shape’s proposed construction should be rejected because it requires that depth data be obtained separately from color image data. (APHB at 17.) As discussed above, that requirement is compelled by the specification and prosecution history.

4. “confocal imaging techniques” (’228, ’456, and ’207 patents, claim 4)

Align interprets “confocal imaging techniques” to refer to three conjugate focal planes illustrated by the Minsky patent. (APHB at 18.) Align’s interpretation is overly broad and encompasses non-confocal techniques, as evidenced by the Confocal Microscopy text by Wilson, which distinguishes confocal and conventional scanning techniques by the point illumination source imaged to a point and detected through a point detector. (HT 1105:2-1106:13, 1152:1-1153:20; RX-0741.0004; RDX-0001.45.)

Non-Infringement of the '228 Patent



In the Matter of Certain Color Intraoral Scanners and Related Hardware and Software (U.S.I.T.C. Inv. No. 337-TA-1091)

RDX-0001.45

(RDX-0001.45.)

Align contends that 3Shape's proposed construction improperly reads limitations from the specification into the claims. 3Shape's proposed construction, however, reflects the confocal imaging technique described in the Color Scanning Patents. Indeed, that technique contemplates the point illumination source (generated by the grating or microlens array) imaged to a point onto the object (illumination spots) and detected through a point detector (pinhole array and image sensor pixel). (JX-0003 at 14:36-16:3.)

Align contends that Dr. Zavislan conceded that a reference he relied on did not require "confocal" to include a pinhole (*i.e.*, point detection). Align selectively omits the text noting that "the basic requirements for the [confocal scanning optical microscope] CSOM are point illumination, point detection, a scanned image, and a confocal lens system." (RX-1100.0014.) Thus, while confocal may connote using the objective lens twice, in the context of confocal scanning systems, confocal has the narrower interpretation requiring point illumination and point

detection, as it has in the Color Scanning Patents. (HT 1152:1-1153:20.) Thus, 3Shape’s construction is proper in light of the specification and understanding of a person of ordinary skill.

5. “image gathering member” (’433 patent, claim 12)

Like with “scanning system,” Align’s shifting interpretation of the structures that constitute the “image gathering member” confirm the term has no plain and ordinary meaning and lacks sufficiently definite structure, subjecting it to §112 ¶6. Dr. Stevenson testified that main illumination source 31 and main optics 41 are the structural components for the “image gathering member.” (HT 580:15-581:20) But Align identifies a 3D image scanner 22, which not only includes illumination source 31 and main optics 41, but also detection optics 60. (APHB at 20.) Align provides no explanation for identification different corresponding structure.

Further, Align’s resort to the specification for the meaning of “image gathering member” highlights the lack of sufficiently definite structure. *TriMed*, 514 F.3d at 1259-60 (“Sufficient structure exists when the claim language specifies the exact structure that performs the functions in question without need to resort to other portions of the specification...”). Other than Dr. Stevenson’s conclusory testimony, Align provides no support that “image gathering member” was a term of art with plain and ordinary meaning. (APHB at 20.)

Align complains about 3Shape’s proposed §112 ¶6 construction as improperly reading in limitations from the specification and requiring the claims to generate depth data separately from the color image data. However, as explained above with “scanning system,” 3Shape’s constructions are supported by the specification and the prosecution history.

6. “selectively map” (’433 patent, claim 12)

Align seeks to rewrite the “selectively map” limitation to simply require a mapping of depth data and image data. This is evidenced by Align’s reference to the portion of the

specification that merely describes “mapping color values to the entity at aligned X-Y points” and not a *selective* mapping as required by the claims. (Align PostHB at 22-23.) Align provides no explanation as to how this portion of the specification discloses selective mapping, rendering the term indefinite.

Further, the passages Align identifies as purporting to “detail[] several approaches by which the image and depth data are correlated with one another” does not show selective mapping. (Align PostHB at 22.) Instead, these passages (JX-0006 13:14-28, 16:24-47) describe the process by which depth data is generated. These passages do not describe mapping, much less selective mapping, of image data to depth data.

The only plausible disclosure of the selectively map limitation is described in column 22 of the ’433 patent, where the specification describes an embodiment where multiple color scans consisting of different monochromatic illuminations are obtained along the depth direction, and a “suitable algorithm[] may be used to form a composite color image of the set of color images associated with a particular z-scan of the object 26 to provide even more precise and accurate color image.” (JX-0006 22:1-27.) But even that disclosure fails to disclose the particularities of the “suitable algorithm” for mapping those color images to the particular z-scan of the object.

Align’s attempts to rewrite the “selectively map” limitation render the term indefinite, since the term “selectively” has been interpreted by Align to have virtually any meaning it desires or no meaning at all.

B. Non-Infringement

1. ’228 Patent

a. Claim 1

Trios 3 does not infringe claim 1 of the '228 patent. Align presented evidence only under its proposed constructions of “scanning system,” “imaging system,” and “processor.” As discussed above, Align’s interpretations are inconsistent with the specification and ignore clear prosecution disclaimers, and should be rejected.

Align did not present evidence of infringement under 3Shape’s proposed constructions of those terms. (*See* HT 471:23-473:15; CDX-0008.31-34.) If 3Shape’s construction is adopted for any such term, there is no evidence that Trios 3 infringes.

**(1) Trios 3 Does Not Include the “Scanning System,”
“Imaging System,” or “Processor”**

Claim 1 of the '228 patent recites a system that “determin[es] the surface topology and associated color of at least a portion of a three dimensional structure.” To do so, claim 1 recites two different systems: (1) “a scanning system configured to provide depth data” and (2) “an imaging system configured to provide two-dimensional color image data.” Because depth data is provided by the scanning system and 2D color image data is provided by the imaging system, claim 1 recites a “processor” for associating the depth data with the color image data to determine the surface topology and associated color of the 3D structure.

Trios 3 uses a fundamentally different approach to determine a color 3D surface topology, avoiding the need for separate systems providing depth data and 2D color image data, and a processor for subsequently associating the two data sets. (HT 952:16-953:14; 1076:14-1079:13.) [REDACTED]

[REDACTED]

[REDACTED] (*Id.*; RX-1104C.0001 [REDACTED])

[REDACTED] JX-0148C.0015 [REDACTED]

[REDACTED]; JX-0079C at 57:24-59:3.)

The color 3D surface topology is derived from the [REDACTED]
[REDACTED]. (RX-
1104C.00001; RX-1098C.0005; HT 457:8-458:17, 820:5-821:19; 946:4-947:2.) [REDACTED]
[REDACTED]
[REDACTED] (HT 457:1-463:4,
820:5-821:19, 946:4-947:2, 1096:22-1098:4; JX-0079C at 166:19-23.) [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]. (RX-1104C.0001; HT 820:5-821:11, 950:14-952:15,
961:14-962:6, 1098:15-1099:24.) [REDACTED]
[REDACTED] (HT 951:6-952:15, 1098:15-1099:24.) [REDACTED]
[REDACTED]. (HT 958:25-
959:11.) [REDACTED]
[REDACTED] the processor need not associate the data sets, because the 3D coordinate and its
corresponding color were derived from the same original data set – [REDACTED]
[REDACTED] (HT 820:5-821:19, 946:4-947:2,
1096:22-1098:4; JX-0079C at 166:19-23.)

**(a) Align Attempts to Recapture Claim Scope
Disclaimed During Prosecution**

During prosecution of the '228 patent, the patentee distinguished U.S. Patent No. 7,098,435 (“Mueller”) from the “scanning system,” “imaging system,” and “processor” because “Mueller discloses a system for obtaining a series of two-dimensional color images of an object and processing those images to obtain a three-dimensional model of the surface of the object.”

(JX-0009 at Align-1091_00003103-4.) Indeed, Mueller explains that by “using the color information from a series of two dimensional color images to derive the three dimensional location in space of the surface points....there is no need to conformally map separately generated color information onto the derived three-dimensional surface points” because “[t]he points are derived from color information and so are already associated with the correct color information.” (RX-0993 at 2:29-41; HT 1078:20-1079:13.)

Trios 3 uses this disclaimed approach to generate a 3D color model of the scanned object. (HT 1076:18-1079:13.) [REDACTED]
[REDACTED]. (HT 952:16-953:14, 1076:14-1079:13; RX-1104C.0001; JX-0148C.0015; JX-0079C at 57:24-59:3.) The patentee’s arguments distinguishing “scanning system,” “imaging system,” and “processor” preclude a finding of infringement against Trios 3. *See Ekchian v. Home Depot, Inc.*, 104 F.3d 1299, 1303-04 (Fed. Cir. 1997) (upholding district court’s finding “that prosecution history estoppel precludes a finding of infringement”).

Align contends that there was no clear disavowal of claim scope. (APHB at 42-43.) This is contrary to established precedent. “The prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution.” *Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1576 (Fed. Cir. 1995). Here, the patentee not only amended the claims to add “scanning system,” “imaging system,” and “processor,” but also distinguished those limitations because the prior art system obtained a series of 2D color images and processed those images to generate the 3D model of the object’s surface. (JX-0009 at Align-1091_00003096, 103-104.) Dr. Zavislan opined that Trios 3 falls within the scope of this

disclaimer, and Align provided no contrary evidence. (HT 1076:14-1079:13.) Thus, the prosecution history precludes finding infringement.

(b) Depth Data is Obtained Separately From Color Image Data

Align contends that the claims and specification do not require depth data to be obtained separately from 2D color image data. (APHB at 42-43.) This is contrary to the claim language and specification. The plain claim language recites two different systems – a scanning system for providing depth data and an imaging system for providing 2D color image data. *See Becton, Dickinson and Co. v. Tyco Healthcare Grp.*, 616 F.3d 1249, 1254 (Fed. Cir. 2010) (“Where a claim lists elements separately, ‘the clear implication of the claim language’ is that those elements are ‘distinct component[s]’ of the patented invention.”). Because the depth data and 2D color image data are provided by different systems, they are obtained separately. (HT 1122:11-1123:15.)

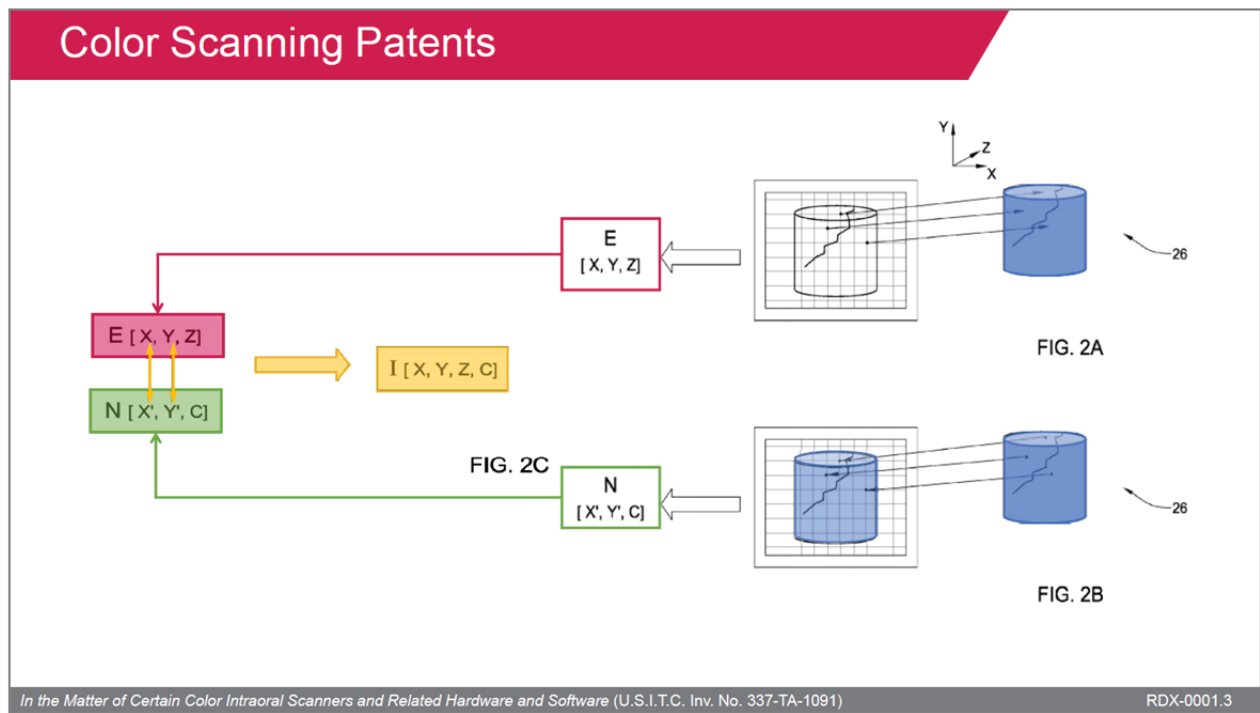
That depth data is separately obtained from 2D color image data is confirmed by the specification. The Color Scanning Patents attempt to solve the problem of associating color information with depth data when color data is obtained using a different method than depth data. (HT1057:12-24.)

Associating color information with three-dimensional objects is not straightforward, particularly when the position information is obtained by using a three dimensional scanning method, while the color information is obtained by using a two dimensional scanning method. The problem of conformally mapping the two dimensional color information onto the three dimensional surface model is difficult and it is common for mismatching of the color with three-dimensional points to occur. Essentially, where two-dimensional color detectors are used for obtaining the color information, it is difficult to accurately associate color information from the detectors with the correct points on the three dimensional surface model, particularly where relative movement between the object and the device occurs between the acquisition of the three-dimensional topological data and acquisition of the two-dimensional image data.

(JX-0003, 1:49-64 (*emphasis added*).) The Color Scanning Patents attempt to solve this problem by obtaining the two data sets within a short time interval, preventing movement of the device between capture of depth data and color image data. (HT 1057:25-1058:19.)

According to the present invention, a two dimensional (2D) color image of the 3D structure that is being scanned is also obtained, but typically within a short time interval with respect to the 3D scan. Further, the 2D color image is taken at substantially the same angle and orientation with respect to the structure as was the case when the 3D scan was taken. Accordingly, there is very little or no substantial distortion between the X-Y plane of 3D scan, and the plane of the image, i.e., both planes are substantially parallel, and moreover substantially the same portion of the structure should be comprised in both the 3D scan and the 2D image. This means that each X-Y point on the 2D image substantially corresponds to a similar point on the 3D scan having the same relative X-Y values. Accordingly, the same point of the structure being scanned has substantially the same X-Y coordinates in both the 2D image and the 3D scan, and thus the color value at each X, Y coordinate of the 2D color scan may be mapped directly to the spatial coordinates in the 3D scan having the same X, Y coordinates, wherein to create a numerical entity I representing the color and surface topology of the structure being scanned.

(JX-0003 at 3:61-4:14 (*emphasis added*) *see also id.* at 5:7-15 (“The device is adapted for providing a time interval between acquisition of said depth data and acquisition of said color image data such that substantially no significant relative movement between said device and said portion occurs.”).) This is confirmed by Figures 2A-2B, which illustrate depth data (E) and 2D color image data (N) being obtained separately. (JX-0003 at Figs. 2A-2B, 13:25-62; HT 1058:20-1061:4.)



(RDX-0001.3.)

Align contends that the specification does not require separate scanning and imaging systems because certain embodiments “show the same components being used to capture depth data and image data.” (APHB at 43.) Although there is overlap of components, all described embodiments in the Color Scanning Patents contemplate that the illumination source for obtaining color image data does not interfere with the illumination source used to obtain depth data, meaning depth data is captured separately from color image data. (HT 1074:19-1076:17;

JX-0003 at 24:43-47 (“In each of the embodiments described herein, the illumination radiation that is used for obtaining the 2D color image is injected into the optical axis OA of the confocal optics 42 without affecting the operation thereof or degrading the 3D image capture.”)

Accordingly, the intrinsic evidence confirms 3Shape’s interpretation that depth data provided by the scanning system is separately obtained from color image data provided by the imaging system.

**(c) Trios 3 Does Not Meet 3Shape’s §112 ¶6
Constructions of “Scanning System,” “Imaging
System,” and “Processor”**

Trios 3 does not meet 3Shape’s §112 ¶6 construction of “scanning system” as it does not include the identified function and corresponding structures.

3Shape’s Proposed Construction

The limitation “scanning system configured to provide depth data” is subject to §112¶6.

Structure: illumination source optically coupled to a grating or microlens array and confocal optics to generate an array of light beams that generates illumination spots on the surface of an object, an image sensor optically coupled to receive each of the returned light beams through a pinhole array and a corresponding single pixel in an image sensor, and a processor programmed to measure the maximum intensity of the returned light beams. (See, e.g., ’228 patent, FIG. 4A and associated description.)

Function: providing depth data separately obtained from two-dimensional color image data

(RDX-0001.35.)

As previously discussed, Trios 3 does not perform this function because depth data is not obtained separately from 2D color image data. Instead, both are derived from the same i [REDACTED]

[REDACTED]. Further, Trios 3 does not include the corresponding structures. The [REDACTED] in Trios 3 is not a grating or microlens array that generates an array of light beams. (HT 1086:13-1087:20.) Trios 3 does not include confocal optics because it does not generate illumination spots on the surface of an object from a point illumination source. (HT 1105:2-20.) Trios 3 does not measure the intensity of returned light beams through a pinhole array because it does not perform point detection. (*Id.*) Trios 3 does not measure the maximum intensity of returned light beams. (HT 947:3-948:10, 1091:24-1092:6.) [REDACTED]
[REDACTED]
[REDACTED]. (*Id.*) [REDACTED]
[REDACTED]
[REDACTED] HT 947:22-948:5.)

Trios 3 also does not meet 3Shape's §112 ¶6 construction of "imaging system" as it does not include the identified function or corresponding structures.

3Shape's Proposed Construction

The limitation “imaging system configured to provide two-dimensional color image data” is subject to §112 ¶6.

Structure: an illumination source that generates at least three different colored light sources to illuminate the surface of an object, and an image sensor optically coupled to receive light from the illumination source reflected from the surface of the object. (See, e.g., '228 patent, FIG. 4A and associated description.)

Function: providing two-dimensional color image data separately obtained from the depth data

(RDX-0001.36.)

As previously discussed, depth data is not obtained separately from 2D color image data. Instead, color and depth data are derived [REDACTED] [REDACTED] Trios 3 does not have an illumination source that generates at least three different colored light sources to illuminate the surface of an object, it includes a white LED. (HT 1085:10-16.)

Trios 3 does not meet 3Shape's §112 ¶6 construction of “processor” as it does not include the identified function or corresponding structures.

3Shape's Proposed Construction

The limitation “processor configured to associate the depth data with the color image data” is subject to §112(b).

Structure: software, firmware, and/or hardware programmed to map the color image data to the depth data. (See, e.g., '228 patent FIG. 2C, 13:20-62)

Function: map depth data with the separately obtained color image data

(RDX-0001.37.)

As previously discussed, depth data is not obtained separately from 2D color image data. Color and depth data are derived [REDACTED], and Trios 3 need not map depth data and color image data. (HT 1096:22-1098:4.) This is unlike the mapping in Figure 2C of the Color Scanning Patents, which maps X-Y coordinates of depth data to X'-Y' coordinates of color image data because depth data and color image data are captured separately.

(2) The Trios 3 Hand-Held Wand Does Not Include the Claimed “Processor”

Align contends that the FPGA processor in the Trios 3 hand-held meets the “processor” limitation because [REDACTED]

[REDACTED] (APHB at 40.) For the “depth data” on the FPGA, Align’s expert identifies [REDACTED]. (HT 462:15-463:4; CDX-0008.19.) This assertion is factually incorrect. [REDACTED]

[REDACTED] (HT: 819:23-821:7; 1099:3-24.) [REDACTED]

[REDACTED] (*Id.*)

Align contends that this testimony is contrary to the “admissions” of 3Shape witnesses Drs. Rosenlund and Hansen. (APHB at 40 n.3) This is simply incorrect. Dr. Rosenlund testified during his deposition that [REDACTED]

[REDACTED] (JX-0074C 57:20-61:13.) He also testified that [REDACTED]

[REDACTED] (JX-0079C 79:13-19.) Likewise, there is no inconsistency with Dr. Hansen’s deposition testimony. As made clear during his testimony, [REDACTED]

[REDACTED] (HT:819:20-821:7 (describing data received by ScanSuite from Trios hand-held), 832:10-22 (describing data received by Trios software from ScanSuite).)

Thus, contrary to Align’s assertions, there is no inconsistent testimony regarding how the [REDACTED]

Further, neither the [REDACTED] are “depth data” as that term is properly understood in the context of the claims and specification. The claimed “depth data” is “of the portion,” which refers to “a portion of the three-dimensional structure” referred to in the preamble of the claim. (JX-0003 25:41-47.) In other words, the depth data is referring to a depth of the object, not to some piece of data that is used to compute the depth of the object. (HT 1068:6-14.) The specification refers to the depth in terms of a Z-coordinate or Z-value. (JX-0003 12:60-6, 3:31-37, 3:53-55, Fig. 2A.) Further, in the context of associating the

depth data with the color image data, the specification is referring to mapping of an (X, Y, Z) coordinate to a color entity (X', Y', C). (JX-0003 3:53-4:14, 13:20-62, Figs. 2A-2C.) Align's attempts to more broadly construe "depth data" as any data related to the computation of a coordinate in object space is inconsistent with the intrinsic record and should be rejected.

[REDACTED]

[REDACTED] (HT: 819:13-821:7, 965:1-966:7, 972:16-975:16, 1092:16-1095:14; 1099:3-24.) Thus, any alleged association would occur on a processor outside the hand-held device, and therefore cannot meet claim 1.

Align contends that 3Shape is improperly limiting the claimed processor "to only one processor that can associate the depth data with the color image data" and that the claims can include more than one processor. (APHB at 43.) Align misses the mark. 3Shape is not arguing that there cannot be more than one processor. Rather, 3Shape is stating the fact that that the alleged association is not so broad as to capture the mere packaging of any data related to depth and color, but must be consistent with the association described in the Color Scanning Patents – which is the association of the depth data in the real-world 3D coordinate with the color data.

(3) Trios 3 Mono Scanners Do Not Infringe

Claim 1 of the '228 patent requires "an imaging system configured to provide two-dimensional color image data" and a "processor configured to associate the depth data with the color image data." Trios 3 Mono scanners are configured with different software that [REDACTED]

[REDACTED] (HT 822:7-11; JX-0079C at 50:15-21.) Thus, it does not "provide two-dimensional color image data" and therefore cannot "associate the depth data with the color image data" as required by claim 1.

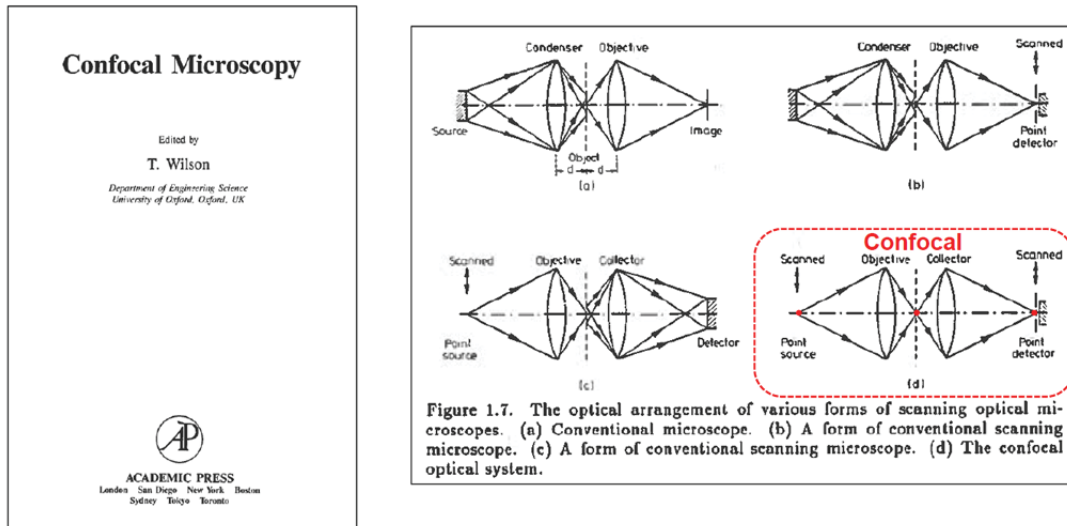
While the Trios 3 Mono scanners can be upgraded to capture color, it requires the Trios 3 Mono scanner to be sent to the 3Shape factory [REDACTED] [REDACTED] (JX-0079C 49:24-50:7, 163:11-22; HT 823:1-10; 968:10-25.) The Trios 3 Mono scanner is then sent back to the customer [REDACTED] [REDACTED] to allow them to access the color functionality. (JX-0079C 163:11-22; HT 968:10-25.) Because modifications are required to enable to color functionality, they cannot be found to infringe. “[T]hat a device is capable of being modified to operate in an infringing manner is not sufficient, by itself, to support a finding of infringement.” *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316 (Fed. Cir. 2001). But even when the Trios 3 Mono scanners are upgraded to color, they still do not infringe for the same reasons set forth above.

b. Claim 4

Claim 4 depends from claim 1 of the '228 patent. Because Align has failed to show that 3Shape infringes claim 1 of the '228 patent, claim 4 cannot be found to infringe. *See Honeywell Int'l. v. Universal Avionics Sys.*, 488 F.3d 982, 995 (Fed. Cir. 2007) (infringement of a dependent claim requires infringement of the claims from which it depends).

Align has failed to show that Trios 3 infringes claim 4 of the '228 patent because Trios 3 does not use “confocal imaging techniques.” Align contends that claim 4 is met because Trios 3 includes three conjugate focal planes – an illumination plane, object plane, and sensor plane. (APHB at 45-46.) Align’s interpretation of “confocal,” however, is overly broad and covers techniques that are non-confocal imaging techniques, which also include three conjugate focal planes. (HT 1104:16-1106:20; RX-0741.0003-04; RDX-0001.45.)

Non-Infringement of the '228 Patent



In the Matter of Certain Color Intraoral Scanners and Related Hardware and Software (U.S.I.T.C. Inv. No. 337-TA-1091)

RDX-0001.45

Confocal imaging is distinguished from non-confocal imaging techniques by a point illumination source that is imaged to a point on the object, which is imaged onto a point detector. (HT 970:7-21, 1105:2-13; 1151:23-1153:22, RX-0741.0004 (distinguishing conventional microscopes in Figures 1.7(a)-(c) from the confocal microscope in Figure 1.7(d)).)

Trios 3 is not confocal because it does not have a point illumination source or point detection. (HT 1106:14-20; 1151:23-1153:22.) There is no point illumination because the LED illumination source in Trios 3 is not focused onto the object because 3Shape is trying to achieve uniform illumination source, nor is it placed at a conjugate focal plane. (HT 944:2-17.) Further, the [REDACTED] in Trios 3 does not act as a point illumination source because [REDACTED]

[REDACTED] HT 945:14-25.)

The fact that Trios 3 is not performing confocal imaging is further evidenced in an e-mail from a consultant for Align to Align's chief scientist, Avi Kopelman. (RX-0201C.) In that e-mail, [REDACTED]

[REDACTED] (*Id.*; RX-0202C.) That paper describes projecting a pattern with a spatial frequency on to the object and observing the portions in focus to obtain optical sectioning – which is a similar technique to [REDACTED] in Trios 3. (RX-0202C.0001; HT 1087:21-1088:8.) Accordingly, Trios 3 does not use a confocal imaging technique.

c. Claim 26

Claim 26 depends from claim 1 of the '228 patent. Because Align has failed to establish that 3Shape infringes claim 1 of the '228 patent, claim 26 cannot be found to infringe. *Honeywell*, 488 F.3d at 995.

2. '456 Patent

a. Claim 1

Claim 1 of the '456 patent contains the same “scanning system,” “imaging system” and “processor” limitations as in claim 1 of the '228 patent. (HT 1129:5-14.) Thus claim 1 of the '456 patent is not met for the same reasons set forth in claim 1 of the '228 patent. (*Id.*)

b. Claim 15

Claim 15 depends from claim 1 of the '456 patent. Because Align has failed to establish that 3Shape infringes claim 1 of the '456 patent, claim 15 cannot be found to infringe. *Honeywell*, 488 F.3d at 995.

Align has failed to show that Trios 3 “conformally map[s] the color image data to the depth data to produce a color, three-dimensional virtual model.” Align contends that this limitation is met because Trios 3 “ensure[s] the dimensions and relationships of the teeth are accurate.” (APHB at 56.) It is unclear as to how the accuracy of the dimensions and relationships of teeth relate to the mapping of color image data to depth data.

Trios 3 does not need to map, much less conformally map, the color image data to the depth data because the color image data and depth data in Trios 3 are [REDACTED] [REDACTED] (HT 820:5-821:19, 946:4-947:2, 1096:22-1098:4, 1106:21-1107:4; JX-0079C 166:19-23.) Further, as discussed in Mueller, when “the color information itself is used to derive the three-dimensional location of the surface points, there is no need to conformally map separately generated color information onto the derived three-dimensional surface points.” (RX-0993 2:33-37; HT 1077:19-1078:19.)

3. '207 Patent

a. Claim 1

Claim 1 of the '207 patent contains the same “scanning system,” “imaging system” and “processor” limitations as in claim 1 of the '228 patent. (HT 1129:5-14.) Thus, claim 1 of the '207 patent is not met for the same reasons set forth in claim 1 of the '228 patent. (*Id.*)

4. '433 Patent

a. Claim 12

Align has failed to show that Trios 3 infringes claim 12 of the '433 patent. In particular, Align has failed to establish that Trios 3 meets the “image gathering member” or the “selectively map” limitations.

(1) “image gathering member”

Trios 3 does not meet this limitation under 3Shape’s construction. 3Shape construes the term as means-plus-function, with a function of generating depth data of a portion of the three-dimensional structure separately from the color image date. (APHB at 59.) The corresponding structure is the same as in 3Shape’s §112 ¶6 construction of the “scanning system” recited in claim 1 of the '228 patent (*Id.*; *see supra* Section III.B.1.a(1)(c).) Trios 3 therefore does not meet the “image gathering member” limitation under 3Shape’s construction for the same reasons

Trios 3 does meet the “scanning system” limitation. (*See supra* Section III.B.1.a(1)(c).) Nor does Trios 3 meet this limitation under 3Shape’s construction under a doctrine of equivalents (“DOE”) analysis. (See APHB at 61.) Trios 3 uses a fundamentally different depth scanning approach than the confocal scanning approach described in the ’433 patent, and is therefore not equivalent for the reasons previously discussed. (*See supra* Section III.B.1.a(1).)

(2) “selectively map the image data to the depth data...”

Trios 3 does not meet this limitation under either parties’ constructions. To the extent this term is not indefinite, 3Shape’s construction is to “map monochrome image data to the depth data such that the monochrome image data is a substantially focused image of that structure.” (*See supra* Section III.A.6.) 3Shape’s construction is based on the only embodiment disclosed by the ’433 specification that could relate to the limitation of “selectively map.” (*Id.*) Trios 3 does not meet this limitation under 3Shape’s construction because, for Trios 3, the color data is

[REDACTED]

[REDACTED] (HT 1108:4-9.) As a result, there is no need to map image data to depth data. (*Id.*)

Align fails to establish that Trios 3 meets this limitation under Align’s proposed construction. Align’s construction attempts to read out the require that the mapping be selective by substituting the term “selectively map” with “matching.” (*See supra* at Section III.A.6.) But Align has failed to establish that Trios 3 meets this limitation even under Align’s improper construction. Align recites a series of steps of how it believes Trios 3 generates a point cloud. Align appears to conclude that something in that series of steps meets the “selectively map” limitation, but provides no explanation of how it is met. (APHB at 63.) For example, Align recites the term “depth” several times – [REDACTED]

(*Id.*) But Align fails to identify what it believes the “image data” and “depth data” to be, how they are matched “based on the plurality of focal lengths and the depth data,” or how the “associated color of the structure portion is in focus relative to the structure portion for a plurality of distances in the depth direction.” (*Id.*) Align has failed to meet its burden to show that Trios 3 meets this claim element under its own construction.

5. 3Shape Did Not Copy iTero or the Color Scanning Patents

Dr. Rune Fisker, 3Shape's first employee, led Trios development starting in 2007-2008. (HT 717:19-23.) Development was slow until Dr. Mike van der Poel, an optics Ph.D., joined 3Shape in 2009. (HT 718:6-15.) The optical design of Trios was set shortly thereafter, in the summer of 2009. (719:19-21.) Dr. Fisker, who also lead 3Shape's patent department, testified that 3Shape did not copy any Cadent (*i.e.*, Align) patents, or iTero, in developing Trios. (HT 718:22-719:1, 756:20-25.)

⁴ The Color Scanning Patents did not issue until 2013-2015. (JX-0003-6.)

product management efforts to “build [a] superior and better product[.]” (HT 711:18-21, 719:3-18.) Align’s VP of R&D, Mr. Relic, confirmed this is normal. (HT 136:11-18.) But 3Shape never obtained or opened iTero, prior to fixing Trios’s optical design. (HT 719:25-720:11.) And when 3Shape did so after fixing the optical design, it did not review the detailed optical system. (HT 720:12-721:13.)

Align raises a circumstantial copying allegation via two old, irrelevant documents created before Dr. van der Poel joined 3Shape. (*See* HT 727:7-739:7, 755:3-756:12; JX-0235C; CX-0236C.) One document shows 3Shape’s competitive intelligence [REDACTED] [REDACTED] (HT 729:10-16, 731:18-733:20; *see also* JX-0235C.) [REDACTED] [REDACTED]. (HT 755:3-8, 952:16-953:14; *see also* JX-0235C; RX-1266C.)⁵ [REDACTED] [REDACTED]. (HT 755:9-756:2; *see also* CX-0236C.)

Align will also point to counsel’s reading into the record portions of internal 3Shape correspondence regarding the Cadent color scanning patent family. Those documents were not admitted because they were not timely on Align’s exhibit list (*see* HT 752:5-753:19), and counsel’s reading proves that 3Shape carefully confirmed freedom-to-operate before releasing Trios Color.⁶ (*See generally* HT 740:1-744:16.)

⁵ The parties inadvertently marked two copies of this document as JX-0235C and RX-1266C.

⁶ For reference, the documents were numbered CX-1598C, CX-1610C, CX-1611C, and CX-1612C.

There is no evidence that 3Shape was aware of the asserted Color Scanning Patents prior to releasing Trios Color in March 2013, and 3Shape “did a lot of freedom-to-operate analysis” with internal patent agents regarding the Cadent patents of which it was aware. (HT 726:4-727:1, 731:18-732:12.) One such patent agent was optics Ph.D. Jesper Bo Jensen. (HT 756:12-7575:24.) The correspondence counsel read was sent in 2010-2011, before 3Shape began development of Trios Color. (HT 740:1-744:16, 756:7-11.) But 3Shape, including Dr. Jensen, [REDACTED] (HT 756:12-758:2.) 3Shape did not implement the features it discussed in the 2010-2011 correspondence. (See, e.g., HT 758:3-10.) And Dr. Fisker dealt the final blow to Align’s copying story when he confirmed that in January 2013, less than two months before release of Trios Color, Dr. Jensen told the Trios team he was [REDACTED] that Trios Color does not infringe Cadent’s color scanning patent family. (HT 757:15-758:2.)

6. 3Shape Has Not Induced Infringement of the Color Scanning Patents

Induced infringement requires an underlying act of direct infringement. *Limelight Networks v. Akamai Techs.*, 134 S.Ct. 2111, 2117 (2014) (“[O]ur case law leaves no doubt that inducement liability may arise ‘if, but only if, [there is]...direct infringement.’”). As discussed above, Align has failed to establish that Trios 3 directly infringes the Color Scanning Patents, and Thus, cannot establish that 3Shape induced infringement.

Align contends that 3Shape “intended to cause the acts that constitute infringement and knew or were willfully blind to the fact the induced acts would constitute patent infringement.” (APHB at 68.) 3Shape was aware of the parent to the Color Scanning Patents – U.S. 7,319,529 – but found it to be different from 3Shape’s approach because it describes taking 2D color data shortly after the 3D image. (HT 952:15-953:14; RX-1266C.0025.)

1. 3Shape Has Not Contributed to the Infringement of the Color Scanning Patents

Contributory infringement requires proof of an act of direct infringement. *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek*, 424 F.3d 1293, 1312 (Fed. Cir. 2005). As discussed, Align has failed to establish that Trios 3 directly infringes the Color Scanning Patents, and Thus, Align cannot establish that 3Shape has contributed to the infringement of the Color Scanning Patents.

C. Domestic Industry (Technical Prong)

1. Legal Standards

“The test for claim coverage for purposes of the technical prong of the domestic industry requirement is the same as that for infringement.” *Certain Access Control Sys. and Components Thereof*, Inv. No. 337-TA-1016, ID at 11 (Oct. 23, 2017) *aff’d*, Comm’n Op. (Apr. 21, 2018). To meet the technical prong of the domestic industry requirement, “the patentee must establish by a preponderance of the evidence that the domestic product practices one or more claims of the patent” either literally or under the doctrine of equivalents. *Id.*

2. Overview of the Align Domestic Products

Align contends the iTero Element, Element 2, and Element Flex practice the Color Scanning Patents, but only provides an element-by-element analysis for the Element, claiming it is representative for the purposes of its technical prong analysis. (HT 496:21-497:7.) But Align and its expert provide no evidence and de minimis testimony for its conclusion:

1 Q Did you also analyze the iTero Element 2 and the
 2 Element Flex as part of your analysis?
 3 A Yes. So kind of like what we saw with the
 4 TRIOS 3, they're slightly different versions, different
 5 bases, and things like that that ultimately don't really
 6 matter much in terms of how we do the intraoral scanning so
 7 they all kind of meet the claim in the same way.

(See HT 497:1-7; APHB at 47, fn4.) Because Align failed to show that differences between Element and Element 2/Flex are immaterial to its technical prong analysis, and failed to provide an element-by-element analysis for Element 2/Flex, Align cannot meet its burden to show that Element 2/Flex practice the Color Scanning Patents.

3. '228 Patent

a. Claim 1

Align has failed to show that the domestic products (“the DI Products”) practice claim 1 of the '228 patent. In particular, Align fails to establish the DI products include a hand-held device comprising “a processor configured to associate the depth data with the color image data” because Align has provided no evidence showing the DI Products literally meet this limitation and is precluded from arguing this limitation is met under DOE.

Align presents a new argument that the DI Products literally meet this limitation when the

[REDACTED]

[REDACTED]

[REDACTED]

(APHB at 52.) But Align has admitted that it failed to provide any evidence supporting this new argument in any timely disclosed expert opinion or deposition testimony evidence. (HT 507:24-508:4, 511:7-512:2.) Thus, any argument that the FPGA literally meets this limitation is unsupported by the record evidence. In

fact, the record evidence shows that [REDACTED] (*i.e.*, depth data) is determined by [REDACTED]

[REDACTED], not the [REDACTED]:



(JX-0077C at 105.) Because the depth data is not determined [REDACTED] does not associate depth data with color image data, as required by claim 1.

Moreover, the only relevant document Align cites, JX-0102C, provides no evidence that the [REDACTED] “combines” depth and color information [REDACTED]. Instead, descriptions in the separate [REDACTED] make clear there is no combining step. (JX-0102C.) [REDACTED]

[REDACTED] (JX-0102C at Align-1091_00684146; HT 1113:14-17.) [REDACTED]

[REDACTED] (JX-0102C at Align-1091_00684146; HT 1113:17-1114:3.) [REDACTED]

[REDACTED] As Dr. Stevenson admits, merely transferring depth and color information through the same path is insufficient to meet this limitation. (HT 566:2-6.) Align has provided no evidence the [REDACTED] combines depth and color information and has therefore failed to meet its burden to show the DI Products literally meet this limitation.

Alternatively, Align argues the “processor” limitation is met under DOE. (APHB at 53.) Align argues the processor location represents an insubstantial difference. (*Id.*) But Align’s argument fails for two reasons. First, Align is precluded from making this DOE argument because applicants amended claim 1 during prosecution to recite a “hand-held device” including the “processor” limitation:

1. (Currently Amended) A system ~~Device~~ for determining the surface topology and associated color of at least a portion of a three dimensional structure, comprising:
a hand-held device comprising:
(a) a scanning system configured to provide ~~means adapted for providing~~ depth data of said portion, the depth data corresponding to a plurality of data points defined on a plane ~~two-dimensional reference array~~ substantially orthogonal to a depth direction;
(b) an imaging system configured to provide ~~means adapted for providing~~ two-dimensional color image data of said portion associated with said plurality of data points ~~reference array; and~~
(c) a processor configured to associate the depth data with the color image data ~~wherein the device is adapted for maintaining a spatial disposition with respect to said portion that is substantially fixed during operation of said scanning means and said imaging means.~~

(JX-0009 at Align-1091_00003096.) This amendment was in response to Examiner’s rejection over prior art, and thus, was made for purposes of patentability.

Claim 1 is rejected under 35 U.S.C. § 102(b) as being anticipated by Mueller et al. (US 7,098,435).
While Applicants do not agree with the rejections and do not acquiesce to any reasoning provided in the Office Action, independent claim 1 has been amended to further expedite prosecution. As amended, claim 1 recites in-part:
a hand-held device comprising:
(a) a scanning system configured to provide ~~depth data of said portion, the depth data corresponding to a plurality of data points defined on a plane~~ substantially orthogonal to a depth direction;
(b) an imaging system configured to provide ~~two-dimensional color image data of said portion associated with said plurality of data points; and~~
(c) a processor configured to associate the depth data with the color image data.

(JX-0009 at Align-1091_00003103-4.) *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 739-40 (2002). By amending the claim to add both a “hand-held device” limitation, and a “processor” limitation included in the “hand-held device,” Align cannot argue that a “processor” not included in the “hand-held device” is equivalent. Through its amendment, applicants “surrendered all subject matter between the broader and the narrower language.” *Id.* at 740-41. Align’s argument also fails because it neither identifies the purported “data link” by the PC processor, nor provides any evidence that such a “data link” is equivalent. (APHB at 53.) Align therefore fails to meet its burden to establish that the DI Products meet this limitation under DOE.

b. Claim 4

Claim 4 depends from claim 1 of the ’228 patent. Because Align failed to establish that the DI Products practice claim 1 of the ’228 patent, Align cannot establish that the DI Products practice claim 4.

c. Claim 26

Claim 26 depends from claim 1 of the ’228 patent. Because Align failed to establish that the DI Products practice claim 1 of the ’228 patent, Align cannot establish that the DI Products practice claim 26.

4. ’456 Patent

a. Claim 1

Align contends the DI Products practice claim 1 for the same reasons provided in its analysis of the ’228 patent, claim 1. (APHB at 56.) Because Align cannot establish that the DI Products practice claim 1 of the ’228 patent, Align likewise cannot establish the DI Products practice claim 1 of the ’456 patent.

b. Claim 15

Claim 15 depends from claim 1 of the '456 patent. Because Align failed to establish that the DI Products practice claim 1 of the '456 patent, Align cannot establish that the DI Products practice claim 15.

5. '207 Patent

a. Claim 1

Align contends the DI Products practice claim 1 for the same reasons provided in its analysis of the '456 patent, claim 1. (APHB at 58.) Because Align cannot establish that the DI Products practice claim 1 of the '456 patent, Align likewise cannot establish the DI Products practice claim 1 of the '207 patent.

Additionally, Dr. Stevenson's bare assertion that "dentists and Align engineers use[] and demo[] the iTero scanners" is unsupported by the record evidence and therefore fails to establish that method claim 1 of the '207 is practiced in the U.S. (*Id.*)

6. '433 Patent

a. Claim 12

Align has failed to show that the DI Products practice claim 12 of the '433 patent. In particular, Align provides a conclusory explanation of how the DI Products meet the limitations of "Element 12.4":

v. Element 12.4:

Dr. Stevenson testified that the two-dimensional image data is the color data that is collected by the image sensor in the iTero, or in the case of depth scanning, [REDACTED]

[REDACTED] (HT:520:10-14; *see also* Domestic Industry – Technical Prong for the '228 patent; JX-0090C at 14.)

(APHB at 66.) "Element 12.4" recites one or more processors that "receive, from the apparatus, two-dimensional image data of the structure portion associated with the two-dimensional reference array for each of a plurality of focal lengths relative to the image gathering member."

(’433 Patent (JX-0006) at 28:13-17.) On its face, Align has failed to establish the DI Products practice the limitations of Element 12.4.

Align also fails to establish that “Element 12.4” is met because the record evidence shows that the DI Products [REDACTED]

The recited “two-dimensional image data” in “Element 12.4” must relate to color data, as the next claim limitation involves selectively mapping “the image data to the depth data...such that the resulting associated color of the structure portion is in focus.” (’433 Patent (JX-0006) at 28:18-23 (emphasis added); HT 1080:14-1081:6.) To the extent Align contends “two-dimensional image data” is met by “[REDACTED]” used for depth scanning, such an interpretation is contradicted by Dr. Stevenson’s testimony (*see* HT 570:4-571:13) and is incompatible with the claim as a whole. Claim 12 recites selectively mapping “the image data to the depth data...such that the resulting associated color of the structure portion is in focus.” (’433 Patent (JX-0006) at 28:18-23.) It would be nonsensical to selectively map monochrome images from the depth scan to the depth data, and such a mapping would not result in the required “associated color” of the structure portion. (’433 Patent (JX-0006) at 28:18-23; APHB at 66.)

The ’433 specification appears to disclose one embodiment where “two-dimensional image data” relating to color data is received for each of a plurality of focal lengths:

of the depth scan. In one mode of operation, the depth scan is obtained by displacing the objective lens 166 along the z-direction in a continuous or stepped motion. Multiple color scans can then be obtained by associating the color sources 377 with the objective lens, so that these are also displaced along the z-direction. Accordingly, as the light sources 377 are moved in the z-direction towards the object 26 during the depth scan, at each different z-position in which a set of images is taken (concurrently with or alternately with the depth scan), each one of the colored illuminations—red, green, blue and intermediate wavelengths—illuminates a progressively deeper part of the object along the z-direction.

(’433 Patent (JX-0006) at 22:3-14; HT 1081:7-1082:15.) Here, multiple color images are captured at different focal lengths and can form a more precise in-focus composite color image:

composite color image at this station. Thus, a plurality of color images can be obtained, each based on a different z-position, so that each illumination wavelength is used to illuminate in focus a different part (depth) of the object 26. Advantageously, suitable algorithms may be used to form a composite color image of the set of color images associated with a particular z-scan of the object 26 to provide even more precise and accurate color image, than can then be combined with the depth data.

(’433 Patent (JX-0006) at 22:19-27.)

The DI Products do not [REDACTED]. Instead, Dr. Zavislan testified they capture [REDACTED] (HT 1112:19-1113:11, 1116:20-1117:6.) Dr. Zavislan’s testimony is uncontested, as Align and its expert admit the DI Products capture [REDACTED], and do not deny that the [REDACTED] are captured [REDACTED]. (See APHB at 51; HT 572:16-573:8.) Thus, there is no dispute that the DI Products fail to meet this limitation.

IV. THE GINGIVAL DEFORMATION PATENTS

The parties agree that the ’470 and ’931 Patents expire May 14, 2019, which is prior to the May 20, 2019 Target Date for completion of this Investigation. As a consequence, there is a

strong likelihood that no remedy may be available to Align on these patents because the Commission cannot issue an exclusion order as to expired patents. Thus, any findings with respect to infringement would be purely advisory in the case where a remedy is not available. (See 3Shape Motion for Partial Termination dated Aug. 2, 2018).

A. Claim Construction

Complainant argues that purported admissions from experts somehow resolve claim construction in their favor. Align, however, ignores the unassailable point that claim construction is a question of law. *Markman v. Westview Instruments*, 517 U.S. 370, 384 (1996). Therefore, the opinion of an expert without legal training that a term denotes an “act” rather than a “step” doesn’t bear on the understanding of those terms in the context of a §112 ¶6 analysis. *See Seal-Flex, Inc. v. Athletic Track & Court Constr.*, 172 F.3d 836, 848 (Fed. Cir. 1999) (J. Rader, concurring).

3Shape has consistently held the position that the claims require a secondary gingival model. Align’s statement that this is “shifting” is mere puffery to disguise the obvious and fatal flaws in Align’s infringement and domestic industry positions. Align’s own expert agrees that neither 3Shape nor Align practices any of the embodiments disclosed in the patent, all of which include a secondary gingival model. (HT. 384:4-25.) Align now seeks to inappropriately expand the claims to capture the technologies actually at issue.

Additionally, despite Align’s attempt to mischaracterize Dr. Saber’s testimony, Dr. Saber has consistently testified that, while the words “secondary gingival model” are not literally part of the claims, the claims require the presence of a secondary gingival model, because that is the only model which the patent teaches as being deformed. (HT. 1029:16-21 (“Q: And you admitted just previously that there is no secondary gingival model required by Align’s proposed

construction. That’s correct, isn’t it sir? A: No. What I said is the word “secondary” is not contained in the construction. Q: Oh, well—A: Literally present in the construction.”)); *compare* (HT. 991:15-992:5 (Dr. Saber testified that all proffered constructions require a secondary gingival model because that’s the only application that is consistent with the teaching of the patent.))

Despite Align’s assertions to the contrary, Dr. Saber never conceded that he was reading limitations into the claim. (HT. 1025:3-23.) Rather, Dr. Saber consistently explained that he applied Align’s proposed constructions as they would be understood by one of ordinary skill reading the patent as a whole. (HT 991:15-992:5). *See also Smart Vent, Inc. v. USA Floodair Vents, Ltd.*, 93 F. Supp. 3d. 395, 412-13 (D.N.J. 2016) (rejecting defendant’s argument that plaintiff’s expert “implicitly rewrote and/or rejected” the court’s claim construction when he provided his understanding of the court’s construction as one of ordinary skill in the art).) Dr. Bergeron confirmed the appropriateness of this approach when he testified that, despite 3D models not being explicitly stated in the asserted claims, he understands the claims to be limited to 3D models, and understands this based on how one of ordinary skill in the art would read the patent specification. (HT 382:25-383:8.)

Most tellingly, despite their repeated insistence that Dr. Saber’s analysis is improper, Align has made no attempt to distinguish or otherwise rebut the plain fact that Dr. Saber’s testimony is squarely within the guidance of Federal Circuit’s opinions in *Virnetx* and *Profoot*. In *Virnetx*, the Federal circuit reaffirmed that claim terms should be read in light of the specification, and further held that claim terms should be understood in a way that preserves their “primary inventive purpose.” *VirnetX, Inc. v. Cisco Sys.*, 767 F.3d 1308, 1316-18 (Fed. Cir. 2014); JX-0069C at 122:4-15 (inventor Pavlovskaja: “this model is precisely what [] the patent

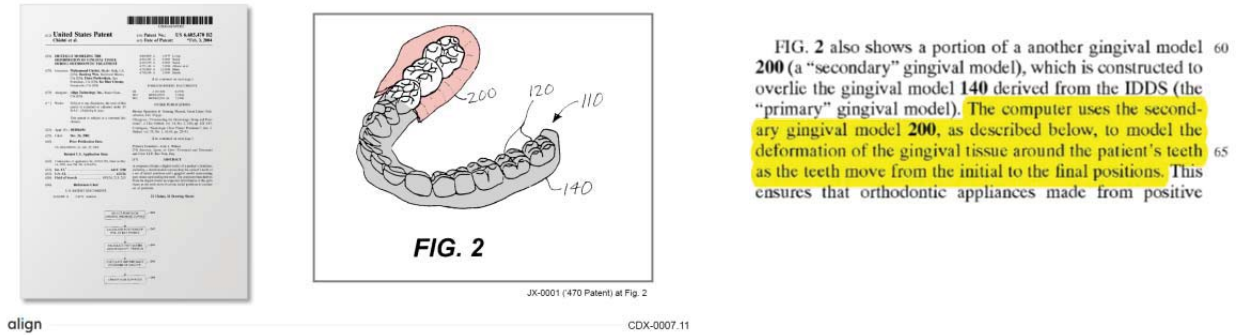
[is] about, this secondary gingival model.”); JX-0082C at 96:10-98:1 (inventor Wen explaining that the addition of thickness via the secondary model is necessary because “if you don’t add the thickness, [the appliance will] pinch [] the gum. That’s why we artificially add a little bit of thickness on [the appliance].”); JX-0046C at 68:15-69:13 (inventor Chishti describing the purpose of the secondary gingival model as reducing soreness for the patient, and agreeing that it is an important feature of the patent.)

The Federal Circuit in *ProFoot* further guided that when, as here, all of the embodiments in the specification describe a claim term as containing specific components, the term should be understood to require those components. *See ProFoot, Inc. v. Merck & Co.*, 663 Fed. Appx. 928, 932-34 (Fed. Cir. 2016) (“When a patent ‘repeatedly and consistently’ characterizes a claim term in a particular way, it is proper to construe the claim term in accordance with that characterization.”) Align further claims that there are additional embodiments that do not use the secondary gingival model, but their own expert Dr. Bergeron clearly testified that all of the embodiments in the patent implement a secondary gingival model. (HT. 383:13-16 (“Q: All of the disclosures and embodiments in the patent use the secondary gingival model as what is being deformed, correct? A: That’s correct”).

Based on these legal principles, which go unaddressed by Align, Dr. Saber’s understanding of the patents was entirely appropriate, and in fact the only permissible application of the available claim constructions.

Furthermore, Align’s own expert, Dr. Bergeron, repeatedly identified item 200 in figure 2 as the “gingival model” discussed in the claims. (HT. 314:7-11; CDX-0007.11)

The Gingival Deformation Patents



The patent specification identifies item 200 as the "secondary gingival model." (JX-0001 3:63-65, Fig 2). As Dr. Saber testified, without the secondary gingival model, the patent merely describes conventional 3D modeling techniques, which were well understood prior to the invention. (HT. 985:9-986:17; and 987:11-25.) Consequently, it is clear that both experts understand the "gingival model" of the patent that is being deformed to refer to the "secondary gingival model" of the specification, and that one of ordinary skill in the art would rely on the specification to inform their understanding of the claims.

B. Non-Infringement

1. Overview of the Accused 3Shape OrthoAnalyzer Software Product

As a threshold matter, Align persists in asserting that Dental System is a properly accused product, based solely on a single software specification sheet which describes Ortho System having "integration" with Dental System. JX-0195C. 3Shape's witnesses consistently testified that this integration only encompasses the Splint Designer module, and includes no accused functionalities. (HT. 714:15-23, 839:5-842:6.) Dr. Bergeron failed to even consider the testimony of 3Shape's witness in coming to his conclusion. (HT 387:8-13.) Based on this testimony, it is clear that none of the accused functionalities are available within Dental System, and therefore it is not properly within the scope of Align's analysis or infringement allegations.

Further, Align's contention that there are "no disputes" about Virtual Setup being a representative product are unfounded. 3Shape has not, and does not now, concede that Virtual Setup is a representative product for the functionalities of 3Shape's accused indirect bonding or Dental System. Nor has Align established any such representativeness.

2. '470 Patent

a. Claim 1

(1) Claim elements 1.1 and 1.2

Align bears the burden of showing that the accused products meet every limitation of the asserted claims. Align's briefing fails to meet this burden. The cited portions of Dr. Bergeron's testimony refer to the [REDACTED] source code files. However, Dr. Bergeron also testified that he "made no effort to identify which 3Shape source code functions correspond to any given element of the asserted patents." (HT. 386:1-19.) Align further identifies the ScanIt Dental program as practicing claim limitation 1.2, but ScanIt Dental is not an accused product nor does Align even allege that it is within an accused product. Thus, taken in total, Align has failed to meet their burden that the accused 3Shape products practice the first two limitations of the asserted claim 1.

(2) Claim elements 1.3 and 1.4

3Shape's products do not practice claim elements 1.3 or 1.4 under any of the proffered constructions. Under the §112(b) constructions, Align's expert Dr. Bergeron admitted that 3Shape's products do not practice any of the algorithms identified in the specification of the '470 patent. (HT. 384:22-25 ("Q: And 3Shape does not implement any of the techniques or embodiments disclosed in the specification; is that right? A: I believe that is right.")) Dr. Bergeron's statement amounts to an admission that 3Shape's products do not contain the acts identified by either 3Shape or Align's constructions. This comports with Dr. Saber's testimony,

based on his review of the source code, that 3Shape does not implement the algorithms described in the specification. (HT. 997:4-6). Dr. Bergeron's conclusory statement on direct examination that 3Shape practices the steps outlined in the specification should be disregarded because his sole evidentiary basis for that opinion is that a control point on a margin line moves along with the gingiva. (HT. 334:20-335:23.) Furthermore, Dr. Bergeron directly contradicted this testimony when questioned about it on cross examination. (HT. 384:22-25 ("Q: And 3Shape does not implement any of the techniques or embodiments disclosed in the specification, is that right? A: I believe that's correct."))

The only remaining question is whether 3Shape practices these limitations under Align's proposed 'plain and ordinary meaning' construction. At the evidentiary hearing, Dr. Bergeron's testimony focused on the presence of a model of teeth and a model of gingiva in the 3Shape software, as shown by his demonstrative slide for that element. (HT. 329-330.)

'470 Infringement

Claim 1: [1.3]

[1.1] A computer program, stored on a tangible storage medium, for use in developing a course of treatment for an orthodontic patient, the program comprising executable instructions that, when executed by a computer, cause the computer to:

[1.2] receive data obtained by scanning a patient's teeth or a physical model thereof, and

[1.3] derive from the received data a digital model of a patient's dentition, including a dental model representing the patient's teeth at a set of initial positions and a gingival model representing gum tissue surrounding the teeth; and

[1.4] derive from the digital model an expected deformation of the gum tissue as the teeth move from the initial positions to another set of positions.

ALIGN's Proposed Plain and Ordinary Construction

4.1.5.1 Virtual Setup (Ortho Planner Only)



Virtual Setup is an option simulating the orthodontic treatment in Ortho Analyzer.

In order to use this option to simulate treatment by moving the teeth, the segmentation of teeth models at the **Preparation** step must be performed first (see the chapter [Segmentation of Maxillary Model](#)). Otherwise, you will get a warning message for unsegmented teeth when clicking

the **Virtual Setup** option:

It is possible to customize the view of the model by using the visualization sliders in the upper right corner:

Slider	Description
	Teeth - allows you to adjust the transparency level of the teeth, or even turn their visualization off.
	Tissue - turns on/off the visualization of the tissue and allows to adjust its transparency.
	Selected tooth - allows to change transparency of the selected tooth.

JX-0196C (2017 Ortho System User Manual at 123) (3Shape_ITC_00039828 at 39928)

See also CX-0855C, CX-0777C

CDX-0007.35

However, if the term “derive” in the claim limitation is not a mere nonce word, and denotes a specific act, Align’s evidence is wholly lacking as to where, if at all, 3Shape’s products actually derive these models. Dr. Bergeron’s testimony is bereft of any mention of derivation, or the acts that constitute derivation (*Id.*).

Further, a fair reading of Align’s construction still requires the presence of a secondary gingival model. Despite Align’s argument to the contrary, the Edit Flexible Tissue tool does not implement the secondary gingival model of the patent. As Dr. Saber explained, [REDACTED]

[REDACTED] (HT. 1003:23-1004:21.) Additionally, Align cannot show, and does not argue, that the Edit Flexible Tissue tool “creates surfaces that connect the gingival curves to each other and

Referring also to FIG. 8, the computer completes the secondary gingival model by creating surfaces 265, 270, 275 that connect the gingival curves 230, 235 to each other and to the base curve 240 (step 510). FIG. 9 shows one technique for creating these surfaces. The computer first selects points 280A–F on each of the curves 230, 235, 240 (step 520). The computer then creates curves 285A–D between these points (step 522) and creates surface segments 290A, 290B that connect these curves (step 524). The points 280A–F selected

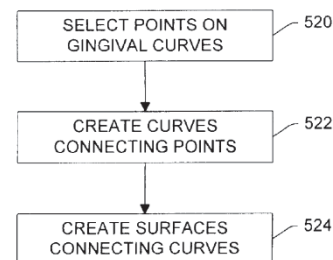


FIG. 9

to the base curve,” and therefore the tool does not actually contain the elements necessary to have a secondary gingival model under the embodiment Align relies on. (JX-0001 at 5:14- 29, Fig 9). In particular, both experts agree that the core function of the secondary gingival model is to overlie the gingiva and add thickness to enhance comfort. (JX:0001 at 3:60-4:5; HT. 383:9-12, 987:11-25.) This is fundamentally different from the Edit Flexible Tissue tool, which [REDACTED] [REDACTED] (JX-0196C at 131; HT 1004:10-21.) As Dr. Saber testified, without the creation of the surfaces in the patent, the splines and control points created in the Edit Flexible Tissue tool were well

understood means of manipulating any digital model, rather than the specific steps of creating the secondary gingival model. (HT. 1003:23-1004:21.)

Beyond the edit flexible tissue function, Dr. Saber confirmed that nowhere in the accused 3Shape products is there a secondary gingival model as required by the patents, and therefore 3Shape cannot meet the claim limitations which require it. (HT. 997:4-999:19). Dr. Bergeron further did not testify or allege that 3Shape practices a secondary gingival model which overlies the gingiva or adds thickness.

Indeed, Dr. Bergeron testified that all of the embodiments within the specification use the secondary gingival model. (HT. 384:4-17.) He further admitted that 3Shape does not implement any of the embodiments in the specification. (HT. 384:22-25.) Taken in combination with Dr. Saber's testimony that one of skill in the art would understand the application of Align's proposed construction to require the secondary gingival model, it is clear that both experts agree that 3Shape does not infringe under Align's construction, when properly read in light of the patent as a whole.

3. '931 Patent

Both experts agree that, save for the "scanning a patient's teeth or a physical model thereof to obtain data" limitation, Claim 1 of the '931 patent contains substantially the same limitations as claim 1 of the '470 patent. (HT. 349:9-13, 1012:16-25.) Consequently, 3Shape's accused products do not infringe claim 1 of the '931 patent for the same reason that they do not infringe claim 1 of the '470 patent.

4. Contributory Infringement

Align cannot show that 3Shape is liable for contributory infringement. Align erroneously claims in their briefing that 3Shape did not provide any evidence of a substantial non-infringing

use. To the contrary, Dr. Saber testified that Ortho System, the accused product, contains numerous non-infringing uses, including the creation of bracket placements, occlusion maps, and arch designs, as well as the diagnosis of overbites and overjets. (HT. 1006 14-17; JX-0196C). Furthermore, Dr. Bergeron confirmed that both Ortho System and Dental System include uses other than the accused functionalities. (HT 387:14-19.) Consequently, Align has failed to proffer sufficient evidence to demonstrate that 3Shape is liable for contributory infringement.

5. Induced Infringement

In the first instance, in order to show induced infringement, Align must show there was a direct infringement by some other party. *Limelight*, 134 S. Ct. 2111, 2117 (2014). Align has not provided any evidence or analysis sufficient to demonstrate that there was a direct infringer, and therefore cannot now assert that 3Shape is liable for induced infringement. Additionally, induced infringement requires a showing of specific intent to cause infringement by another. *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 766 (2011). Align's reference to the Patterson Dental declaration is insufficient evidence of 3Shape's intent to meet this burden. Further, it is unclear what, if any, weight Dr. Bergeron's testimony with respect to the declaration is intended to offer, as his technical expertise doesn't afford him any special insight into the business practices of 3Shape or Patterson Dental, or the knowledge that 3Shape had. Even if Dr. Bergeron's testimony were credited, it is contradicted by Dr. Saber's testimony that Align has not shown that 3Shape possessed the requisite intent. (HT. 1006:23-1007:3.) Taken as a whole, Align has not proffered sufficient evidence to demonstrate that 3Shape is liable for induced infringement of the asserted patents.

C. Domestic Industry (Technical Prong)

1. '470 Patent

Align's domestic industry analysis is deficient for much the same reason as their infringement analysis.

With respect to the § 112(b) constructions, Dr. Bergeron himself confirmed that Align's products do not practice any of the embodiments disclosed in the specification. (HT. 384:15-21.) Thus, by their own expert's admission, Align's products do not implement the acts underpinning the steps of deriving a model of dentition or deriving an expected deformation.

Under Align's construction, they once again rely on the mere presence of margin lines and control points as proof of a secondary gingival model. Align cannot point to the creation of a surface between those points, because those points are overlaid onto the already created model, and used as control mechanisms. Additionally, while Align relies solely on the user interface video (CPX-0066C), Dr. Saber reviewed the source code files and could find no structure corresponding to the secondary gingival model of the patent. (HT. 1015:6-1016:9.) The testimony of Align's source code developer further confirms that, while there are [REDACTED] [REDACTED] related to the modeling of gingiva, they are only used [REDACTED] and both [REDACTED] (JX-0070C at 38.)

2. '931 Patent

Both experts agree that, save for the "scanning a patient's teeth or a physical model thereof to obtain data" limitation, Claim 1 of the '931 patent contains substantially the same limitations as claim 1 of the '470 patent. (HT. 349:9-13, 1012:16-25.) Consequently, Align's products do not practice claim 1 of the '931 patent for the same reasons that they do not practice claim 1 of the '470 patent.

V. ECONOMIC PRONG

3Shape does not dispute that Align is a large company with U.S. facilities and employees. However, sheer size is not a proxy for domestic industry. Similarly, the fact that Align invested in plant and equipment or labor in the U.S. does not establish domestic industry. Rather, Align must show significant U.S. investments related to articles practicing the Asserted Patents.

The Color Scanning Patents were allegedly developed in Israel by a former Cadent employee fifteen years ago (JX-0003; JX-0004; JX-0005; JX-0006), and Align has not meaningfully updated the patented technology since the Element was launched in 2015. (*See also* HT 96:15-97:5, 133:2-134:10, 144:16-145:21; RX-0655C.0005-6.)

The Gingival Deformation Patents were allegedly developed by four long-gone Align employees twenty years ago (JX-0001; JX-0002), and the original Treat software, released in 1997 or 1998, used the same gingival deformation technique. (JX-0046C 90:8-19; JX-0060C 79:22-25.)

Despite this long-ago development, Align claims a domestic industry. According to Align, the domestic articles for the Color Scanning Patents are Element, Element 2, and Element Flex. For the Gingival Deformation Patents, Align claims the Invisalign System, “a method for treating malocclusion based on a series of custom manufactured, clear plastic, removable aligners.” (JX-0093 at Align-1091_00577136.) These aligners, which Align so proudly displayed during the hearing, practice no Asserted Patent. (RX-0026.) To design and visualize clear aligner treatment plans, Align employs Treat, ClinCheck, and Outcome Simulator software. These programs, which are not sold, are the only aspects of the Invisalign System allegedly practicing the Gingival Deformation Patents. (*See, e.g.*, HT 614:13-15.)

Align repeatedly invokes “realities of the marketplace” as a crutch to assign numerous domestic investments to the iTero scanners or the “Invisalign System” that are either not cognizable or are so tangential to the domestic products that they deserve little to no weight. The realities of the marketplace undermine, rather than support, Align’s position.

The vast majority of Align’s U.S. employees are Invisalign sales and marketing, or perform G&A functions. Align’s employees that research, develop, and manufacture the hardware for Element are in Israel, while software for Element is programmed in Israel and Russia. (HT 129:20-130:20, 131:19-132:6, 133:15-17, 263:8-11.) Thus, the employees and facilities, and investments therein, with the most relevant and direct tie to Element and the Color Scanning Patents are abroad.

Similarly, Align’s employees most directly related to Clincheck, Treat, and Outcome Simulator are programmers in Russia. (HT 127:9-128:5, 129:13-19; JX-0065 25:8-22.) Even Invisalign, which is not properly a domestic article, is manufactured in Mexico, with treatment planning in Costa Rica, China, and Germany. (HT 121:23-25, 155:9-11, 263:12-15, 419:1-16.)

Align’s entire business is geared toward Invisalign; iTero is an afterthought. (HT 86:17-24, 90:22-93:20, 95:13-96:4, 401:5-9 (“Q. Can you describe Align.... A. ...Align simply straightens teeth with plastic.”), 424:16-18.) Approximately 90% of Align’s revenue is Invisalign, and Invisalign expenditures similarly outweigh iTero expenditures approximately 9:1. (HT 249:3-7; JX-0093; JX-0142; JX-0145.) In Investigation No. 337-TA-833 Align relied on its ordinary course accounting to show a domestic industry in Invisalign, in 2014, with respect to patents unrelated to those asserted here. But now, Align needs to prove a domestic industry in other products, with respect to other patents, in 2017. Given the primacy of Invisalign and the fact that these other products use old technology that was engineered, researched, developed and

manufactured abroad, Align departed from its prior strategy in an effort to manufacture a domestic industry.

First, Align came up with a theory that approximately ten U.S. executives and marketing employees “control” iTero development by setting product requirements like the color of the device, despite the actual engineers being in Israel and Russia. Second, Align allocated [REDACTED] or more of its U.S. expenditures to iTero based on qualitative concepts like “value added to Invisalign” and “synergies,” and on reallocating Invisalign employees as “split” between iTero and Invisalign. Third, Align counted all Invisalign investments in its domestic industry based on these “synergies,” despite admitting that the “Invisalign System” and “Invisalign clear aligners” do not practice any Asserted Patent. By employing these unsupported strategies, Align irredeemably overcounted domestic investments. Align then went further, assessing significance by comparing these overcounted U.S. investments, in the aggregate, to limited foreign investments, in order to further overstate.

Given Align’s overcounting, both Align’s quantification of expenses and significance comparisons are flawed. Align’s failure to make a significance comparison based on each Asserted Patent (or set of patents) and each domestic article (or set of domestic articles) renders Align’s analysis even more unreliable.

In Align’s view, 3Shape and Mr. Green have turned the analysis into a rigid “accounting prong” exercise.⁷ That is not the case. (*See, e.g.*, 1211:20-24.) 3Shape’s argument is that Align’s quantification of investments is so demonstrably contrary to its ordinary course

⁷ Both experts agree that the first step in the economic prong analysis is reliably quantifying investments allocable to each domestic article (an “accounting” exercise). (HT 615:22-616:7, 1175:2-20.)

documents, and thus unreliable, that it infects both steps of Align’s economic prong analysis. In the first step, it is impossible for either party or the ALJ to know what cognizable investments Align made in each domestic article. And because Align’s unreliable quantification has so obscured the quantity of cognizable investments, it is impossible for either party or the ALJ to assess whether Align’s investments are significant in the second step. (HT 1240:14-21.)

Finally, Align faults Mr. Green, an expert in accounting, finance and valuation issues associated with IP, for not making the ultimate legal conclusion regarding significance. It is black-letter law that it is improper for Mr. Green to make the ultimate legal conclusion. *Certain Electronic Devices With Image Processing Systems, Components Thereof, and Associated Software*, Inv. No. 337-TA-724, 2011 ITC LEXIS 833, Order No. 25 at *6-7 (March 4, 2011) (“Expert testimony that consists of legal conclusions cannot properly assist the trier of fact...legal conclusions offered in expert testimony should be excluded from the evidentiary hearing”); Fed. R. Evid. 702.⁸

Mr. Green properly explained Align’s ordinary course financial records, making clear that Align’s evidence is entirely inconsistent with these records, and thus, unreliable. On the other hand, Align’s expert, Mr. Bakewell, provided no opinions that help the parties or ALJ better understand the issues – he merely served as a conduit to read numbers into the record and give voice to Align’s attorney argument about synergies and significance, and his testimony deserves no weight.

⁸ Align also intimates that Mr. Green admitted that Align spent [REDACTED] on iTero R&D in 2017. (APHB at 112-113.) What Mr. Green said is Align “allocated more than [REDACTED] dollars to iTero R&D in 2017.” (HT 1237:11-20.) This is no admission that the allocation was proper, particularly after Mr. Green explained why Align’s allocations are unreliable. (HT 1210:5-1216:7.)

A. Align Vastly Overcounts Expenditures

1. Align's Allocation Methodologies are Unreliable

Align argues that “all that is required is the use of reasonable allocations” and documentary corroboration of time allocations is not required. (Align PHB at 95-96 (citing *Certain Solid State Storage Drives, Stacked Electronics Components, and Prods. Containing Same*, Inv. No. 337-TA-1097, Comm’n Op. at 21 (June 29, 2018)).) This misses the point.

In the 1097 Investigation, the Commission ignored the lack of documentary corroboration because “Respondents did not provide specific persuasive evidence showing that [Complainant’s witness]’s time estimates...are unreliable.” *Id.* 3Shape, on the other hand, has presented evidence that the allocations and testimony from Mr. Bakewell, Ms. Kling, Mr. Morici, and Mr. Relic are unreliable.

a. Align's Ordinary Course Financials

As a public company, Align files quarterly and yearly reports with the SEC using Forms 10Q and 10K. Under GAAP, Align reports two different operating segments – Scanners (iTero) and Clear Aligners (Invisalign). (JX-0093 at Align-1091_00577136-140; HT 1175:14-1176:10.) According to Align, “[o]perating segments are defined as components of an enterprise for which separate financial information is available that is evaluated regularly by the Chief Operating Decision Maker (‘CODM’), or decisionmaking group, in deciding how to allocate resources and in assessing performance.” (JX-0093 at Align-1091_00577224.) Align reports two segments because that is how its CODM, CEO Joe Hogan, “views and evaluates [Align’s] operations as well as allocation of resources.” (*Id.*; *see also* HT 1175:21-1176:22.) This is consistent with Align’s “management” approach. (HT 1176:23-1177:5.) Both Mr. Hogan and Align’s CFO, John Morici, certify that each 10K or 10Q “fairly presents, in all material respects, the financial

condition and result of operations of [Align].” (JX-0093; JX-0146) Thus, these reports are reliable. (HT at 248:8-249:2.)

Align has reported these two segments since acquiring Cadent in 2011. (HT 1177:6-9.) From 2011-2016, Align reported segments at the gross profit level. (HT 1177:6-19.) “In the fourth quarter of 2016, management decided to change the way it internally assesses the performance of our reportable segments by including income from operations....” (JX-0146.0150.) This more granular reporting reflects that Align’s management assesses Align’s allocation of resources and performance between iTero and Invisalign at the operating profit level. (HT 1177:10-1178:2.) This is important because it requires Align to track operating expenses by segment – gross profit minus operating expenses equals income from operations (*a.k.a.* operating profit or operating margin). (HT 1178:22-1179:10; *see also* JX-0093 at Align-1091_00577224; HT 1206:4-24 ([REDACTED]); RX-0223C.)

Align’s Ordinary Course Reporting: 2017 Form 10-K				
For the Year Ended December 31,				
Net revenues	2017	2016	2015	
Clear Aligner	\$ 1,309,262	\$ 958,327	\$ 800,186	
Scanner	164,151	121,547	45,300	
Total net revenues	\$ 1,473,413	\$ 1,079,874	\$ 845,486	
Gross profit				
Clear Aligner	\$ 1,019,563	\$ 747,494	\$ 628,187	
Scanner	97,384	67,800	11,923	
Total gross profit	\$ 1,116,947	\$ 815,294	\$ 640,110	
Income from operations				
Clear Aligner	\$ 564,648	\$ 411,817	\$ 371,113	
Scanner	49,613	37,498	(12,337)	
Unallocated corporate expenses	(260,650)	(200,394)	(170,142)	
Total income from operations	\$ 353,611	\$ 248,921	\$ 188,634	
Depreciation and amortization				
Clear Aligner	\$ 21,581	\$ 13,742	\$ 9,842	
Scanner	4,385	3,871	3,839	
Unallocated corporate expenses	11,773	6,389	4,323	
Total depreciation and amortization	\$ 37,739	\$ 24,002	\$ 18,004	

JX-0093 (2017 Form 10-K).

RDX-0007. 11

(RDX-0007.11 (citing JX-0093) (*emphasis added*); HT 1203:3-1206:24.) The operating expenses allocated to segments include sales, marketing, customer care, R&D, and other. (HT 1204:1-1206:24.)

Not all of Align's expenses are allocable to a segment. The unallocated costs "include stock-based compensation, costs related to IT, facilities, human resources, accounting, legal and regulatory, and other separately managed general and administrative costs outside of the operating expenses." (JX-0093 at Align-1091_00577224; HT 1203:7-25.)

The allocated operating expenses in the Scanner segment provide a natural starting point for quantifying domestic investments.^{9,10} (See HT 1211:20-1212:8; *see also id.* at 243:2-13 (payroll spreadsheets [REDACTED] are the "starting point...to understand [] overall expenses and...split [] time across Invisalign versus iTero").) Meanwhile, unallocated costs are non-product costs of running a business typically non-cognizable for domestic industry. *Certain Dynamic Random Access Memories, Components Thereof, and Prods. Containing Same*, Inv. No. 337-TA-242, 1987 ITC LEXIS 170, Comm'n Op. at *103-04 (Nov. 1987) (excluding "the value added by upstream and downstream production activities, as well as royalties and overhead, and general and administrative expenses" from domestic industry analysis). Instead of using this springboard into a reliable analysis, Align devised unsupported allocations to skew expenses toward iTero. (HT 238:11-239:1.)

b. The [REDACTED] Allocation

⁹ These Scanner operating expenses would need further analysis because they are worldwide and include "services." (See, e.g., HT 642:5-14 (removing "services"), 1204:1-1207:2.)

¹⁰ The Clear Aligner operating expenses relate to the entire Invisalign System and thus, vastly overstate worldwide operating expenses for Clincheck, Treat, and Outcome Simulator.

This allocation prepared by Mr. Morici allocates [REDACTED] of investments to iTero, and [REDACTED] to Invisalign (*i.e.*, allocates 100% of Align’s investments to iTero or Invisalign). (HT at 249:8-15, 682:14-20.) This allocation is inappropriate and unreliable for many reasons.

First, Align has products other than iTero scanners and Invisalign clear aligners. (JX-0093 at Align_1091_00577139.) For example, Align also sells disposable sleeves (HT 201:22-24; 202:15-203:15) and iTero models and dies (*id.*), makes OrthoCAD software available for download (HT 204:8-205:7), and provides iTero labside software (HT 1045:1-7). Each of these products are provided separate from the iTero scanner. Either Mr. Morici’s allocation ignores the products or counts investments in them, even though they do not practice the Asserted Patents. (RX-0026.)

Second, Mr. Morici derived his allocation by looking at budgeting and forecasting, “how we’re driving the business,” and “investing in the future.” (HT 232:3-15, 264:12-18.) But looking forward is inappropriate in a domestic industry analysis, which looks backward from Complaint filing absent extraordinary circumstances. *Certain Television Sets, Television Receivers, Television Tuners, and Components Thereof* (“TVs”), Inv. No. 337-TA-910, Comm’n Op. at 56-57 (Oct. 30, 2015) (“The Commission has considered evidence subsequent to the filing of the complaint only...when a significant and unusual development has occurred after the complaint has been filed.”). Mr. Bakewell, confusingly, views looking backward as a “drawback.” (HT 644:4-8.)

Third, Mr. Morici claims he came to his allocation by looking at the time and effort Align’s employees put in. (HT 1210:4-13). [REDACTED] (HT 167:17-168:1.) Regardless, Mr. Morici’s allocation is applied to over [REDACTED] Align employees

from 2015-2017, of whom Mr. Morici spoke to three, none in R&D. (HT 232:3-15, 250:19-251:4.)

Fourth, Mr. Morici's allocation allegedly applies to every single Align investment uniformly from 2015-2017. (HT 1210:19-1211:1.) But Mr. Morici did not join Align until November 2016 and did not consider 2015 data. (HT 223:14-20, 250:12-18.) This uniform application is inconsistent with typical practice, including Align's. (HT 1211:2-19; JX-0093.0092 (in Align's ordinary course, "each allocation is measured differently based on the specific facts and circumstances of the costs being allocated").))¹¹

Certain operating expenses are attributable to operating segments and each allocation is measured differently based on the specific facts and circumstances of the costs being allocated."

Align 2017 Form 10-K, p. 92

(RDX-007.51 (quoting JX-0093) (*emphasis added*); HT 1210:19-1211:7.)

Finally, as Mr. Green explained, less than [REDACTED] of Align's allocated operating expenses are Scanner; the other [REDACTED] are Clear Aligner:

¹¹ Align claims that Mr. Bakewell relied on the testimony of "Ms. Kolli, Ms. Singer, Mr. Stubbs, [and] Mr. Williams" (APHB at 101-102) but that testimony is not in the record.

Align's Ordinary Course Financial Reporting

"Costs not specifically allocated to segment income from operations include various corporate expenses such as stock-based compensation and costs related to IT, facilities, human resources, accounting and finance, legal and regulatory, and other separately managed general and administrative costs outside the operating expenses."

"Certain operating expenses are attributable to operating segments and each allocation is measured differently based on the specific facts and circumstances of the costs being allocated."

Align 2017 Form 10-K, p. 92

Align's 2017 Allocations of Operating Expense

	Scanners & Services	Clear Aligner	General Corporate
R&D			
Sales			
Marketing			
General & Admin			
Total			
% of Allocated			

JPX-0012C (Q417 10-Q Segment Report); JX-0093 (2017 Form 10-K).

RDX-0007. 16

(RDX-0007.16 (citing JX-0093, JPX-0012C) (*emphasis added*).) Mr. Morici's allocation of [REDACTED] of investments to iTero is off by a factor of 3. Align claims unallocated costs account for the difference (HT 237:3-14), but, as explained above, those costs are non-cognizable. Further, for unallocated costs to bridge the gap, [REDACTED] must be attributed to Scanners. This makes no sense since just [REDACTED] of the allocated expenses are Scanners.

In its prior ITC Investigation 337-TA-833, Align relied on ordinary course operating expenses. (HT 1208:24-1209:13.) Mr. Morici's explanations for deviating from Align's certified financials are inconsistent with contemporaneous documents, casting further doubt on the reliability of his allocation and testimony:

- Mr. Morici testified that "tak[ing] overall expenses...and assign[ing] those to either Invisalign or iTero...[is] a process that...[Align] do[es]n't normally do." (HT 229:2-15.) Align does, at least every quarter (10Qs) and year (10Ks). (HT 1207:6-1208:23.)

- Mr. Morici, when asked whether Align [REDACTED] [REDACTED] (HT 255:17-19.) Align does. (HT 1178:11-1179:17; RDX-0007.11 (citing JX-0093).)
- Mr. Morici testified that Align “do[es] not talk about operating margin at a segment level.” (HT 236:9-10.) Align does. (HT 1207:6-1208:23; *see also id.* at 1178:22-1179:10; JX-0093 at Align-1091_00577224.)
- Mr. Morici testified that Align “do[es]n’t allocate [] operating expenses to each segment.” (HT 237:3-6.) Align does. (HT 1207:6-1208:23; *see also id.* at 1178:22-1179:10, 1204:1-1206:24, 1208:4-23; JX-0093 at Align-1091_00577224; RX-0223C; RDX-0007.19C (shown below, excerpting JX-0349C) ([REDACTED]) (*emphasis added*).)

Confidential Business Information - Subject to Protective Order

Align’s Ordinary Course Financial Reporting



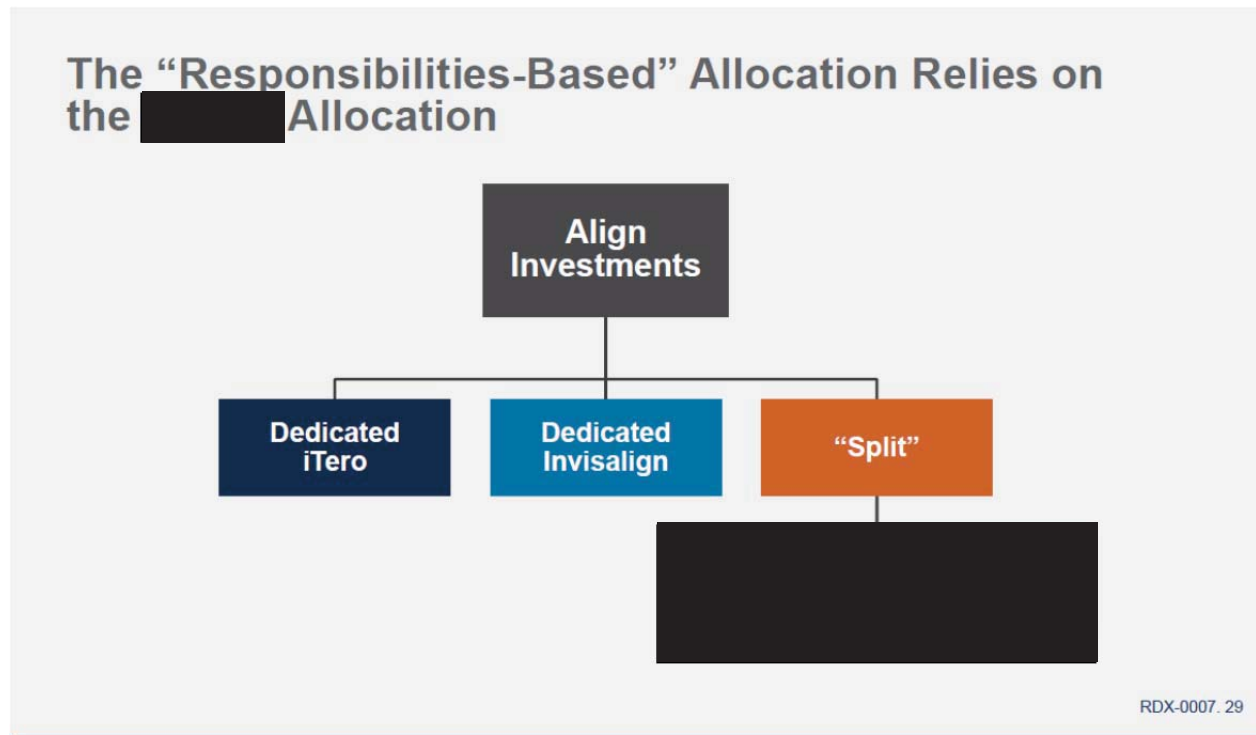
JX-0349C (Presentation Deck) RDX-0007. 19. C

Based on the inconsistencies identified herein, the [REDACTED] allocation is unreliable. (HT 1212:9-16.)

c. The “Responsibilities-Based” Allocation

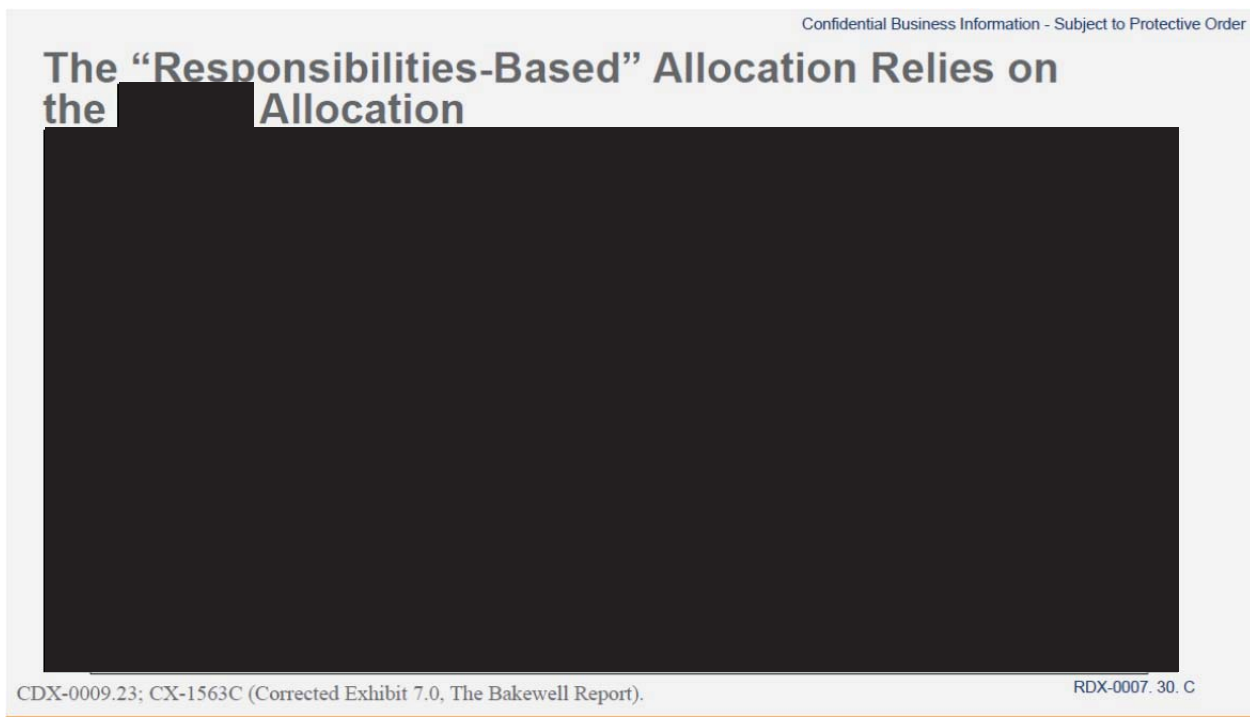
Late in fact discovery, to distance itself from Mr. Morici’s unreliable allocation, Align created a “responsibilities-based” allocation based on a “headcount analysis.” (HT 108:15-18; 211:22-212:2.) Ms. Kling and four colleagues categorized over [REDACTED] Align U.S. employees for 2015, over [REDACTED] for 2016, and all [REDACTED] for 2017 as “iTero dedicated,” “Invisalign dedicated,” or “iTero-Invisalign Split.” (See JPX-0001C; HT 106:11-15, 169:1-12.)

The analysis, however, does not allocate the “split” employees (over [REDACTED] of the categorized employees) to the domestic articles. Instead, Align applied the [REDACTED] allocation to split employees, making the responsibilities-based allocation as unreliable as the [REDACTED] allocation itself. (See JPX-0001C; HT 687:16-688:9, 1212:17-1213:9.)



(RDX-0007.29; HT 1212:17-1213:3.)

Furthermore, the headcount spreadsheet is inconsistent with, and attempts to re-write, Align's ordinary course records. In segment reporting, Align categorizes employees as Scanner or Clear Aligner using "cost centers." (HT 107:6-9, 233:1-12.) Align relied on these categorizations in the 833 Investigation. (HT 1235:4-12.) But here, Ms. Kling recategorized many employees from Clear Aligner cost centers (*i.e.*, Invisalign dedicated) into her "split" group. (HT 1213:13-1214:4.) Indeed, Ms. Kling's analysis categorizes zero of over [REDACTED] "other technical marketing" and "other technical sales" employees as "[f]ocused on Invisalign":



(RDX-0007.30C (citing CDX-0009.23; CX-1563C) (*emphasis added*); HT 1213:4-1214:4.) This absence of “technical” marketing and sales employees for the product accounting for [REDACTED] of Align's revenue, in Align's biggest geographical market, is unbelievable, particularly given that one group in this category is “Invisalign field sales reps.” (HT 183:20-184:16.) Similarly, according to Ms. Kling, Align has [REDACTED] U.S. trainers, product management employees, clinical

education employees, or sales employees dedicated to Invisalign. (HT 175:9-16, 181:25-182:10.) Almost every employee Ms. Kling categorized as “split” is allocated to the Clear Aligner segment in Align’s ordinary course financials. (HT 1241:23-1242:12, 1213:13-1214:4.)

Align argues this “split” category was necessary because there is no “split” segment in Align’s financials. But, as Mr. Green explained, expenses and revenues are already split between Scanner and Clear Aligner. (HT 1229:8-21.)

Ms. Kling claimed the headcount spreadsheet “estimates the time that U.S. employees spend” working on iTero or Invisalign, but it contains no indication of time spent. (*Compare* HT 167:2-16 *with* HT 217:6-8, JPX-0001C.)¹² And it was prepared based on personal knowledge of just five individuals (HT at 169:1-12), which is unlikely to reliably reconstruct three years of work for over [REDACTED] employees, particularly considering Ms. Kling [REDACTED] [REDACTED], and she did not consult any documentation. (HT 211:3-21.) Ms. Kling did not even assess whether an employee’s category should change over the three-year span. (HT 171:17-23.)

Predictably, as with the [REDACTED] allocation, just months later its creators are undermining its reliability. For example, Mr. Relic would re-categorize many employees. (HT 110:7-111:3.) This immediate second-guessing demonstrates the allocation’s *ad hoc*, unreliable nature.

Finally, in an effort to legitimize the allocations using accounting terms, Mr. Bakewell and Mr. Morici began falsely calling them “activity-based costing,” further undermining their credibility. (HT 238:11-239:1, 261:9-19, 644:4-22, 649:22-650:4, 651:5-652:4, 700:15-701:4, 703:19-704:16.) Mr. Green, a licensed CPA and CMA who has implemented activity-based

¹² Mr. Bakewell testified this was a “person-by-person” analysis, which it was not. (*Compare* HT 169:16-170:11, 171:5-13 *with* 648:11-21, 649:9-18.)

costing systems, described the concept and explained that Align’s allocations are not activity-based costing. (HT 1171:23-1173:8, 1214:5-22.)

In Mr. Green’s expert opinion, based on the inconsistencies discussed herein, the responsibilities-based allocation is unreliable. (HT 1213:4-9.)

d. The “Revenue-Based” Allocation

In a further signal that its prior allocation methods are suspect, Align began using this third different allocation at the close of fact discovery. Revenue-based allocations are traditionally used by manufacturing entities because in that instance, revenue and investments correlate – as you sell more, you spend more to make more. (HT 1215:11-22.) Here, Align manufactures the domestic articles abroad, and a revenue-based allocation is inappropriate for the activities Align claims to perform in the U.S. (HT 1215:25-1216:7.)

While Align’s revenue-based allocation is the most reliable of the three, it is still unreliable based on the “timing mismatch” identified by Mr. Green. It is more unreliable with respect to Clincheck, Treat, and Outcome Simulator because they are not sold, and Mr. Bakewell used clear aligner revenue instead. (HT 642:15-22.)

2. Align Overcounts Its Investments

a. Invisalign

After eleven months, Align still does not know whether Invisalign clear aligners are claimed domestic articles. Align argues that “has never been Align’s contention” (APHB at 98), but just a few sentences later, argues that “the relevant domestic industry includes the Invisalign

System, not just...the clear aligner.” (*Id.* at 99.)¹³ Despite Align’s statement to the contrary, 3Shape has always disputed whether the “Invisalign System” (including Invisalign clear aligners) is a proper domestic article. (*See, e.g.*, 3PreHB at 442-44; APHB at 98.)¹⁴

None of the Asserted Patents cover the “Invisalign System” or clear aligners. (*See, e.g.*, RX-0026.) Further, Invisalign is not a component of a complete downstream product, and the realities of the marketplace do not support counting Invisalign investments. Align appears to contend that the “digital ecosystem” is the “complete downstream product” of which Invisalign is a component. Therefore, as alternate theory, Align contends that all investments count towards every patent. The evidence contradicts this.

Align’s digital ecosystem is not one product. iTero and Invisalign are accounted separately by Align using the “Scanner” and “Clear Aligner” segments. (*See, e.g.*, JX-0093.) They are sold separately. (HT 101:2-3, 101:6-9, 203:25-204:2.) They are used separately – iTero scans can be used for non-Invisalign treatments and Invisalign cases can be started with traditional impressions or non-iTero scanners. (HT 101:6-22, 102:5-16, 136:5-10, 192:25-193:5, 193:12-194:8, 203:25-204:2, 213:3-6, 254:14-17.) The “digital ecosystem” does not require iTero scans. (HT 89:9-16 (“it can be any patient data in digital form”), 101:8-9, 212:23-6.) Roughly [REDACTED] of iTero scans are not for Invisalign, and [REDACTED] of Invisalign cases involve a PVS impression. (HT 193:12-194:8, 253:2-254:3, 254:14-17; RX-0244C.)

¹³ Clear aligners are part of the Invisalign System. (*See* JX-0093 at Align-1091_000577136 (“The Invisalign System is a proprietary method...based on...clear plastic, removable aligners.”).)

¹⁴ If the alleged domestic article is not more than Clincheck, Treat, and Outcome Simulator, why would Mr. Bakewell alternatively allocate just Clincheck, Treat, and Outcome Simulator? (HT 666:2-15.)

Align's digital ecosystem is, at most, a future objective, not a current "reality of the marketplace," and the testimony of Messrs. Bakewell, Hogan, Morici, and Relic trying to link iTero and Invisalign is unreliable because it is contradicted by contemporaneous documents.

Mr. Bakewell testified that "total digital platform" and the headcount spreadsheet "is how Align views its business" and "runs its business." (HT 643:2-11, 649:22-650:4.) Mr. Hogan testified that Align does not treat iTero and Invisalign separately "in the sense of every day in the way we manage." (HT at 403:12-16.) Mr. Morici testified that "when we think about how we run our business, we are looking at a combined ecosystem." (HT 229:18-19.) Mr. Relic testified that the cost centers [REDACTED]

[REDACTED] All of this is directly contrary to what Align tells the SEC:

The management approach uses the internal reporting used by the CODM for decision making and performance assessment as the basis for determining our reportable segments.

...

The reportable operating segments are based on how our CODM views and evaluates our operations as well as allocation of resources.

(JX-0093 at Align-1091_00577224; *see also* HT at 1176:16-22 (segment reporting "means that Mr. Hogan, when he's...assessing how to manage the business, he's looking at it from the point of view of iTero on the one hand, and Invisalign, on the other").) Mr. Morici confirmed that "segment reporting [] should be a reflection of how management thinks about managing the business." (HT 236:14-17.) In other words, Align's segment reporting, based on separate cost centers for iTero and Invisalign, is exactly how Align's management, including Messrs. Hogan

(the CODM), Morici, and Relic, make decisions, assess performance, evaluate operations, and allocate resources – *i.e.*, how they view, manage, and run the business.

In fact, over the entire 2015-2018 period Align relies upon, Align’s management has not believed iTero and Invisalign were well integrated. When Mr. Hogan joined Align in June 2015, he “didn’t feel the businesses were well integrated.” (HT at 414:1-5.) And in April 2018, Mr. Pascaud stated Align [REDACTED] [REDACTED] lamenting that Align [REDACTED] and [REDACTED] (HT 1394:10-1395:2; JX-0334.)

Even if Align does have a fully-realized digital ecosystem, its reliance on Invisalign is still flawed. Apple has a fully-realized digital ecosystem, and nobody serious would argue that investments in iTunes or AirPods count toward a domestic industry in the iPhone. Similarly, Mr. Relic analogized Invisalign to “medicine.” (HT 95:24-96:4.) AstraZeneca could not count its investments in Crestor if it claimed a domestic industry in an EKG machine.

Align’s claims of a digital ecosystem are forward-looking and unreliable, and do not support counting Invisalign investments in the domestic industry.

b. Future Scanners

In allocating 100% of its activities to iTero or Invisalign, Align counted investments in future scanners, [REDACTED] [REDACTED] (HT 134:11-136:1, 206:4-22, 220:19-21, 1044:7-25; RX-0575C; RX-0578C; RX-0655C.) Thus, application of the [REDACTED] allocation or the responsibilities-based allocation results in improper inclusion of expenses related to these future products.

c. Sales and Marketing and G&A

To determine facilities and equipment investments, Align multiplied total period costs for the San Jose and Raleigh facilities by its three different allocations. (APre-HB at 101-104.) This use of the revenue-based and [REDACTED] allocations captures investments related to corporate officers, finance, HR, and IT, which are housed in San Jose. (*See, e.g.*, HT 239:23-240:5.)

Approximately [REDACTED] of the San Jose and Raleigh employees are sales, marketing, and G&A.¹⁵ These groups are not product-related, nor are the facilities expenses associated with them. While the Commission has credited such investments in certain cases, when they constitute the overwhelming majority of investments they are given little to no weight. *TVs*, Inv. No. 337-TA-910, Comm’n Op. at 73-74 (Oct. 30, 2015) (“the mere marketing and sale of products in the United States is insufficient to constitute a domestic industry”). Applying the responsibilities-based allocation fares no better, over [REDACTED] of claimed investments are still sales and marketing. (HT 1218:22-1219:14.) To give them *gravitas*, Align calls them “technical” sales and marketing, but some of these employees’ activities are non-technical, traditional sales and marketing. (*See, e.g.*, HT 162:15-24 (Ms. Kling performs “commercial marketing”), 1219:15-1220:1.) Still, Align counts 100% of their expenses, despite the fact that Mr. Bakewell excluded “non-technical” sales and marketing employees. (HT 611:12-612:3, 1220:2-8.) While Align claims not to be a “mere importer,” this overcounting shows that most of Align’s plant and equipment expenses relate to sales and marketing and G&A, which are typically non-cognizable standing alone.

¹⁵ Filtering column U in JPX-0001C by US-HQ and US-NC shows [REDACTED] employees housed in San Jose and Raleigh. Further filtering column AC by Sales, Marketing, and G&A shows that [REDACTED] of the employees fall within these groups.

To the extent a portion of Align’s San Jose and Raleigh facilities are related to product development and R&D, application of the [REDACTED] allocation or the responsibilities-based allocation sweeps in investments related products not alleged to practice the patents, such as Align’s future scanners, sleeves, models and dies, OrthoCAD, and aspects of the Invisalign System beyond Treat, ClinCheck, and Outcome Simulator.

d. Tangential Activities

To allocate labor costs to the Color Scanning and Gingival Deformation Patents, Align purports to narrow the number of employees to those relevant to iTero and Invisalign. This method, however, counts numerous activities that are at best, tangential to the patented technology, and are entitled to little or no weight. *Certain Integrated Circuit Chips and Prods. Containing the Same*, Inv. 337-TA-859, Comm’n Op. at 40, 48-49 (Aug. 11, 2014) (“The more closely related the domestic activities are to the patented technology, the greater may be the weight of the activities in determining whether they constitute a domestic industry.” Moreover, [REDACTED] of these labor expenses relate to sales and marketing. (HT 1218:22-1219:14.) *Certain Home Vacuum Packaging Prods*, Inv. No. 337-TA-496, 2004 ITC LEXIS 332, ID, at *269 n. 45 (Dec. 16, 2003) (investments that “fall more appropriately into the realm of ‘marketing and sales’” “would not carry any weight”). As described above, their characterization as “technical” sales and marketing does not alleviate Align’s overcounting.

B. Align Failed To Show Significance

1. Quantitative

Given the rampant overcounting, the quantification of plant and equipment, and labor, presented by Mr. Bakewell are unreliable and preclude assessment of quantitative significance.

(HT 1240:14-21.) Further, Align’s quantitative significance analyses overstate numerators and understate denominators to skew the results.

a. Plant and Equipment

Both comparisons described in Align’s Post-Hearing Brief utilize numerators that aggregate costs for all Asserted Patents. (APHB at 105; *Compare* HT 655:14-656:6 (discussing CDX-0009.27), 656:7-24 (discussing CDX-0009.28) *with id.* 689:151-690:1 (CDX-0009.27-28 present unallocated domestic costs).) And both comparisons utilize denominators that only include some of Align’s foreign facilities. (*See* JX-0093 at Align-1091_00577161 (listing only “significant” facilities).)

Further, Align’s [REDACTED] in U.S. “period costs” include over [REDACTED] in rent, which is not “depreciation,” while its foreign period costs omit rent, though certain foreign facilities are leased. (*See, e.g.*, HT 689:3-13; JX-0093 at Align-1091_00577161; CDX-0009.27.)

b. Labor

Even with the overcounted U.S. investments, Align’s quantitative labor comparisons yield aggregates of less than [REDACTED] and a range of [REDACTED] with respect to the individual employee groupings. (*See, e.g.*, HT 672:12-25; CDX-0047-48.) These are not quantitatively significant.

Align’s intentionally skewed comparisons, combined with the aforementioned overcounting, render the analysis unreliable to demonstrate quantitative significance.

2. Qualitative

Align references “realities of the market place,” context, the digital ecosystem and synergies in an effort to show significance. However, the context of Align’s business undermines, rather than supports, significance. The reality is that work directly related to

development and production of Element, Treat, ClinCheck and Outcome Simulator take place in [REDACTED]. The Element wand is produced, and the scanner assembled, in Israel. (JX-0093 at Align-1091_00577141.) Additionally, Element hardware is R&D'd in Israel and Element software is R&D'd in [REDACTED]. (HT 129:20-130:20, 131:19-132:6, 133:15-17, 263:8-11.) ClinCheck, Treat, and Outcome Simulator are programmed in [REDACTED]. (HT 127:9-128:5, 129:13-19; JX-0065 25:8-22.) The direct relation between the activities in Israel and Russia and the domestic products is demonstrated by the cost centers associated with those facilities.

Align employs [REDACTED] across Israel and Russia. (HT 127:9-130:11.) The majority of these employees' cost centers bearing a direct relationship to the domestic products including: [REDACTED] [REDACTED] (HT 127:9-131:22; JPX-0001C.) None of the R&D cost centers in the U.S. bear such direct relation to the domestic products. Rather the R&D cost centers on which Align relies are tangentially related to the domestic products, if at all. For example, R&D employees in the U.S. work on things like developing clear aligner polymers, a mobile photo uploader, APIs for third party scanners, and Align's Doctor Portal website. (HT 121:5-123:4, 123:10-19, 124:9-126:14, 172:1-10, 172:23-174:10, 202:15-203:15.)

RX-0361C and RX-0656C, weekly status reports of activities [REDACTED], respectively, further demonstrate those facilities' direct relationship to iTero hardware and software, Treat, ClinCheck, and Outcome Simulator. No similar documentation outlining R&D activities in the U.S. was identified by Align.

In attempting to bootstrap U.S. activities to iTero development, Ms. Kling and Mr. Relic testified that U.S. employees create [REDACTED]

[REDACTED] (HT 146:15-147:7, 176:21-179:1.)

However, this testimony overstates U.S. employees' role in the process, particularly in relation to foreign employees.

RX-0062C is the product requirement specification for Element. (HT 1042:22-1043:17; RX-0618C.) [REDACTED]

[REDACTED] (*Id.*) The [REDACTED]
[REDACTED]. (*Id.*) At the beginning of 2018, the team responsible for creating product requirement specifications consisted of a [REDACTED] employees reporting to Ms. Kling, and [REDACTED] of them were abroad. (HT 207:4-20.) [REDACTED]
[REDACTED] (HT 209:7-14.)

RX-0572C is the project plan for the iTero Element 2, the follow on to the original Element. [REDACTED]
[REDACTED] (HT 214:10-215:16.)

RX-0575C shows the [REDACTED] that Ms. Kling testified about. [REDACTED]
[REDACTED] (*Compare* RX-0575C with JPX-0001C.) The product manager drives the [REDACTED] (HT 177:11-14.) The iTero Element was announced around April 2015, after which development began on the Element 2 and the Flex, which were released in 2018. (HT 96:15-97:5; 1043:18-20.) [REDACTED]
[REDACTED] (RX-0572C.0002; HT 1043:18-1044:4.) Thus, for the relevant time period for Align's domestic industry analysis [REDACTED]
[REDACTED] has been driven by a foreign employee.

Finally, the OGM, which is the executive leadership team for iTero and provides oversight for the product development roadmap for the iTero business unit [REDACTED]

[REDACTED]

(HT 209:24-210:24.) The managing director of the iTero business unit is now [REDACTED]

[REDACTED] (HT 209:18-23.)

Because the true R&D with respect to the domestic products happens abroad, Align's U.S. investments in plant and equipment and labor purportedly related to engineering and product development are not significant.

While a value-added analysis is not required, because the iTero scanner is developed and manufactured abroad, the clear-aligners are manufactured in Mexico, the treatment planning for the clear aligners happens abroad, and the Treat, Clincheck and Outcome Simulator applications are programmed abroad, this Investigation demands such analysis. With respect to R&D, it is unclear how much value tangential activities such as creating web portals, mobile apps, or researching new polymers add to iTero or Treat, ClinCheck, and Outcome Simulator. Similarly it is unclear how much value [REDACTED]

[REDACTED] (RX-0062C.0016 at 9.2) add to the products where the relevant hardware and software engineering takes place abroad. It is also unclear how much value clinical trainers and technical sales and marketing add when training is not required and the scanners are designed to be intuitive (HT 216:1-218:18; RX-0062C.0016 at [REDACTED] [REDACTED]) and the wands are designed to be plug and play to eliminate on-site repairs (HT 201:22-202:14).

The closest Align comes to any sort of value added analysis is to point to an increase in Invisalign cases, or "lift," for doctors with an iTero scanner and claim that the [REDACTED]

[REDACTED] (APHB at 109-110; HT 190:3-13, 250:4-7, 405:11-17.) But the only evidence of lift is a single study, for which Align paid and defined objectives (HT 190:3-23), that disclaims causation and explains why the lift has no relationship to iTero, as opposed to another scanner. (JX-0084 at Align-1091_00116011-12; *see also* HT 250:4-7.) Even if the phenomenon were true, at best it shows value-added to the Invisalign System from domestic activities, not to iTero. With respect to U.S. employee compensation, Mr. Bakewell's statements are subjective, speculative, and completely ignore the fact that the [REDACTED]

[REDACTED]

[REDACTED]

C. Conclusion

Align has continually changed allocations and theories, but Align cannot "repeatedly change its position...and then rely on the position that best suits its needs when it comes to the hearing." *TVs*, Inv. No. 337-TA-910, ID at 173 (Mar. 5, 2014). Regardless, none of Align's allocation methods are reliable. Coupled with its overcounting of non-cognizable activities, Align's quantification of domestic investments makes its entire analysis unreliable.

When it assesses quantitative significance, Align aggregates and inflates the numerators, undercounts the denominators, and obscures the investments actually counted. And qualitatively, Align ignores that the articles allegedly practicing the Asserted Patents are engineered, researched, developed, and manufactured abroad, claiming tangential U.S. activities as high "value-added."

Align has not proven it satisfies the economic prong.

VI. REMEDY AND BONDING

A. LEO

If the ALJ recommends an LEO, 3Shape respectfully requests that the “form, scope, and extent of the remedy” include the carveouts identified in 3Shape’s Pre-Hearing Brief and a certification provision. (See 3Pre-HB at 478-81 (providing Commission authority and describing relevant carveouts).)¹⁶

B. CDO

A CDO is inappropriate because 3Shape does not maintain “commercially significant inventory” in the U.S. *Certain Integrated Repeaters, Switches, Transceivers and Prods. Containing Same*, Inv. No. 337-TA-435, Comm’n Op. at 27 (Aug. 16, 2002).

3Shape does not “maintain any units of Trios in the [U.S.] that are for sale” and the only units 3Shape maintains in the U.S. are for warranty and replacement or demonstration purposes. (HT 1160:6-14, 1162:2-7.) Align suggests that 3Shape “[REDACTED] confirming its ability to stockpile,” Align provided no evidence that 3Shape intends to do so. (APHB at 114.) This number [REDACTED] because of 3Shape’s recently implemented rapid replacement program, which guarantees a defective scanner “can be swapped within 48 hours.” (HT 1160:15-1161:4.)

Align also asserts that units reserved for 3Shape’s warranty program “could be used potentially for sales,” that “warranty is a form of sales,” and that 3Shape did not provide evidence “that the U.S. inventory would not be converted to units for sale.” (APHB at 114.) But

¹⁶ Align’s assertion that “a limited exclusion order is appropriate because the “public interest factors enumerated in 19 U.S.C. § 1337(d) do not preclude [its] issuance” is premature and inappropriate; public interest was not delegated to the ALJ. (APHB at 113; Comm’n Notice at 2 (Dec. 14, 2017).) 3Shape will address public interest if the Commission finds a violation.

3Shape's VP of Supply Chain, Mikael Petersen, explicitly confirmed that these units are not for sale and there are no circumstances under which 3Shape would sell them. (HT 1161:5-10.) Mr. Green explained that "inventory" typically refers to goods that "are available for sale" – *i.e.*, not units reserved for warranty. (*Id.* at 1221:9-20.) Accordingly, these units are neither "commercially significant," nor "inventory."

Align mischaracterizes 3Shape's import stipulation as well. First, Align assumes the number of units held at 3Shape's Branchburg facility is significant. (APHB at 114, JX-0389C.) But Align ignores that these units are not sold, and therefore, not commercially significant. (*See* HT 1160:9-1162:7.) Furthermore, the units identified in JX-0389C do not represent the number of fully assembled Trios units in the U.S., but are components such as wands and carts. (*See* JX-0389C at Appendix B (listing [REDACTED] among products held at Branchburg facility).) Thus, Align's claim that 3Shape has "[REDACTED] units of Trios 3" in Branchburg vastly misinterprets and overstates the evidence.

If a CDO is granted, it should be subject to the same carveouts sought with respect to a LEO; the warranty and repair units described herein are regularly excluded from a CDO. *See, e.g., Certain Sys. for Detecting and Removing Viruses or Worms, Components Thereof, and Prods. Containing Same*, Inv. No. 337-TA-510, Comm'n Op. at 6 (Aug. 23, 2005).

Finally, although a CDO can address domestic conduct, the Accused Software are not "articles that...infringe" since they are software flashed down from the Internet. "[W]hen there is no importation of 'articles' there can be no unfair act, and there is nothing for the Commission to remedy." *ClearCorrect*, 810 F.3d at 1290. Accordingly, Align has not established that a CDO is appropriate with respect to the Accused Software.

C. Bonding

Align has not met its burden to establish that any bond, let alone a 100% bond is appropriate. Although 3Shape and Align both sell intraoral scanners, [REDACTED]. (HT 86:19-24, 401:8-9, 422:15-18; JX-0055C 38:17-41:3, 99:1-10; JX-0343C.) Thus, the alleged harm to Align from Trios-iTero competition is overstated. Align's suggestion that a bond is necessary to protect Align from alleged harm with respect to products outside the scope of this Investigation (*i.e.*, Invisalign clear aligners) is also inappropriate and misconstrues the purpose of bond.

Align claims that "where a price comparison is not practical and there is no evidence of a reasonable royalty rate, a 100 percent bond may be necessary." This is only true where, unlike here, a Complainant expends some effort to demonstrate that neither method produces a reliable bond. For example, Mr. Bakewell claimed that a "price comparison is not a practical approach because the parties have different business models." (APHB at 116; *see* HT 677:10-13 ("3Shape sells through distributors, whereas Align has a direct sales model.").) But Align and Mr. Bakewell ignored Align's sales that are, in fact, conducted through a reseller [REDACTED]. (HT 421:25-422:5.) Further, Align has not, nor can it, show that [REDACTED] to warrant issuance of any bond. *See, e.g., Certain Access Control Sys. and Components Thereof*, Inv. No. 337-TA-1016, RD (Oct. 23, 2017).

Similarly, Mr. Bakewell reviewed only one intercompany agreement, found it was "very different than the situation here," and concluded a 100% bond was appropriate. Align cannot claim that calculating a bond amount is impractical without presenting any evidence that it even attempted a relevant analysis, and then assert it is entitled to a 100% bond. *See Certain*

Polyimide Films, Prods. Containing Same, and Related Methods, Inv. No. 337-TA-772, ID at 326-27 (May 10, 2012).

VII. CONCLUSION

For the reasons set forth above and in 3Shape's initial post hearing brief, Align has failed to show a violation of Section 337.

Certification pursuant to Ground Rule 1.6: The undersigned counsel hereby certifies that this brief contains 19,987 words according to Microsoft Word's word count feature, and thus, complies with the word limit set by Ground Rule 14.2.

Date: October 12, 2018

Respectfully submitted,

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United States International Trade Commission
Investigation No. 337-1091
Certain Color Intraoral Scanners and Related Hardware and Software

CERTIFICATE OF SERVICE

I, Bilal L. Iddinn, hereby certify that on October 12, 2018 true and correct copies of the foregoing document were served upon the following parties as indicated below:

<p>The Honorable Lisa R. Barton Acting Secretary to the Commission U.S. International Trade Commission 500 E Street, S.W. Washington, D.C. 20436</p>	<p><input checked="" type="checkbox"/> Via Electronic Filing <input checked="" type="checkbox"/> Via Overnight Hand Delivery</p>
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United States International Trade Commission
Investigation No. 337-1091
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CERTIFICATE OF SERVICE

I, Bilal L. Iddinn, hereby certify that on October 19, 2018 true and correct copies of the foregoing document were served upon the following parties as indicated below:

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